

**TRANSMITTAL LETTER TO THE UNITED STATES
DESIGNATED/ELECTED OFFICE (DO/EO/US)
CONCERNING A FILING UNDER 35 U.S.C. 371**

13221-00013

U.S. APPLICATION NO. (if known, see 37 CFR 1.5)

09/890501

INTERNATIONAL APPLICATION NO.

INTERNATIONAL FILING DATE

PRIORITY DATE CLAIMED

PCT/US00/02341

29 January 2000 (29.01.00)

01 February 1999 (01.02.99)

TITLE OF INVENTION Apparatus and Method for Detecting Anomalies in Human Tissues

APPLICANT(S) FOR DO/EO/US Farid Soulier and Jeffrey L. Garwin

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☐ This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.
4. ☐ The US has been elected by the expiration of 19 months from the priority date (Article 31).
5. ☒ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
 - a. ☐ is attached hereto (required only if not communicated by the International Bureau).
 - b. ☐ has been communicated by the International Bureau.
 - c. ☒ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
 - a. ☐ is attached hereto.
 - b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
7. ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
 - a. ☐ are attached hereto (required only if not communicated by the International Bureau).
 - b. ☐ have been communicated by the International Bureau.
 - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
 - d. ☒ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371 (c)(3)).
9. ☐ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. ☐ An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11 to 20 below concern document(s) or information included:

11. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☒ A **FIRST** preliminary amendment.
14. ☐ A **SECOND** or **SUBSEQUENT** preliminary amendment.
15. ☒ A substitute specification.
16. ☐ A change of power of attorney and/or address letter.
17. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821 - 1.825.
18. ☐ A second copy of the published international application under 35 U.S.C. 154(d)(4).
19. ☐ A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).
20. ☐ Other items or information:

APPLICATION NO. (if known, see 37 CFR 1.53)
09/890501INTERNATIONAL APPLICATION NO
PCT/US00/02341ATTORNEY'S DOCKET NUMBER
13221-0001321. ☒ The following fees are submitted:**BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)):**Neither international preliminary examination fee (37 CFR 1.482)
nor international search fee (37 CFR 1.445(a) (2)) paid to USPTO
and International Search Report not prepared by the EPO or JPO **\$1000.00**International preliminary examination fee (37 CFR 1.482) not paid to
USPTO but International Search Report prepared by the EPO or JPO **\$860.00**International preliminary examination fee (37 CFR 1.482) not paid to USPTO
but international search fee (37 CFR 1.445(a)(2)) paid to USPTO **\$710.00**International preliminary examination fee (37 CFR 1.482) paid to USPTO
but all claims did not satisfy provisions of PCT Article 33(1)-(4) **\$690.00**International preliminary examination fee (37 CFR 1.482) paid to USPTO
and all claims satisfied provisions of PCT Article 33(1)-(4) **\$100.00****ENTER APPROPRIATE BASIC FEE AMOUNT =****CALCULATIONS PTO USE ONLY**

\$ 860.00

\$ 0.00

Surcharge of **\$130.00** for furnishing the oath or declaration later than ☐ 20 ☐ 30
months from the earliest claimed priority date (37 CFR 1.492(e)).

CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE	
Total claims	105 -20 =	85	x \$18.00	\$ 1,530.00

Independent claims	10 -3 =	7	x \$80.00	\$ 560.00
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MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ \$270.00	\$ 0.00
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TOTAL OF ABOVE CALCULATIONS = \$ 2950.00☒ Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above
are reduced by 1/2. + \$ 1475.00**SUBTOTAL =** \$ 1,475.00Processing fee of **\$130.00** for furnishing the English translation later than ☐ 20 ☐ 30
months from the earliest claimed priority date (37 CFR 1.492(f)). \$ 0.00**TOTAL NATIONAL FEE =** \$ 1,475.00Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be
accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). **\$40.00** per property + \$ 0.00**TOTAL FEES ENCLOSED =** \$ **1,475.00**Amount to be
refunded: \$

charged: \$

- a. ☒ A check in the amount of \$ 1,475.00 to cover the above fees is enclosed.
- b. ☐ Please charge my Deposit Account No. _____ in the amount of \$ _____ to cover the above fees.
A duplicate copy of this sheet is enclosed.
- c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any
overpayment to Deposit Account No. 50-1089. A duplicate copy of this sheet is enclosed.
- d. ☐ Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. **Credit card
information should not be included on this form.** Provide credit card information and authorization on PTO-2038.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR
1.137 (a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO:

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NAME

42,248

REGISTRATION NUMBER

PATENT
ATTORNEY DOCKET: 13321.00013

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent application of: :
: Group Art Unit
Souluer and Garwin :
: Not Yet Assigned
:
Int'l Application No.:
PCT/US00/02341
Int'l Filing Date:
29 January 200
Serial No.: : Examiner:
: Not Yet Assigned
Filed: Herewith :
:
For: Apparatus and Method for Detecting :
Anomalies in Human Tissue :

PRELIMINARY AMENDMENT

Assistant Commissioner for Trademarks
Washington, D.C. 20231

Dear Sir:

This preliminary amendment is being filed in the above-referenced U.S. national phase patent application before substantive review of the application. It is requested that the substitute specification enclosed be entered into the application prior to substantive review by an Examiner.

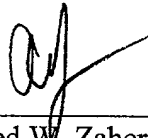
Should it be deemed that additional fees are due, the Commissioner is authorized to charge any fee, or credit any refund, associated with this response to Deposit Account No. 50-1089.

REMARKS

The substitute specification is marked as Exhibit A; the marked-up version of the specification is marked as Exhibit B, and the revised drawings are marked as Exhibit C..

Please note that no new matter is being added to the application. The changes made to the specification were merely correcting typographical errors and were made for clarification purposes.

By:



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- 1 -

**APPARATUS AND METHOD FOR DETECTING
ANOMALIES IN HUMAN TISSUE**

Invented By
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Jeffery L. Garwin

REFERENCE TO RELATED APPLICATION

This application claims priority to U.S. Patent Application Ser. No. 09/241,193 entitled "Apparatus for Detecting Very Small Breast Anomalies" filed on February 1, 1999, which is incorporated herein in its entirety by reference.

FIELD OF THE INVENTION

This invention relates to apparatus and methods for detecting human tissues, and in particular for detecting very small anomalies such as tumors in human tissue such as a breast. The invention includes tissue mapping, the detection of tissue anomalies, generating an electrical signal and graphical data corresponding thereto, and automated tissue imaging and sampling for characterizing detected tissue anomalies.

BACKGROUND OF THE INVENTION

The early detection of anomalous human tissue, and in particular detection of undesirable tissue such as fat, fibrous tumors, or cancerous tissue is a much felt need. For example, recent findings indicate that one out of eight women will develop breast cancer, the second leading cause of death in women. The earliest indication of breast cancer generally is the occurrence of a painless lump, sometimes associated with nipple discharge and skin retraction. Unfortunately, later, more obvious and less survivable

indications of cancer are generally due to metastases to bone, brain, lungs and liver. Accordingly, early detection of anomalous tissue and tissue changes is essential for improvement of survivability and effective treatment. Attempts at early detection through monthly self-examinations and mammography have proven beneficial but have not satisfied the need for more effective methods of early detection and corresponding treatment.

By way of example, if small lumps, less than 20 mm, can be detected early they can then be diagnosed by a biopsy and treated should the lump be found to be malignant. Accordingly, early detection would allow for less invasive treatment such as a lumpectomy with possible radiation treatment of axillary nodes making less likely the need for a modified radical mastectomy with axillary node dissection. In addition through early treatment, the five-year survival rate maybe improved by as much as 85 percent. Absent early detection, distant metastasis are likely reducing survival rates to 10 percent or even less. The present invention address this very critical need.

Although early detection is essential, it can be difficult to achieve even by skilled physicians. Monthly self examinations have been shown to be helpful, particularly when followed by the examination of a physician in the event something is detected. It is, however, difficult and often unlikely for an unskilled person to do a thorough examination or detect very small lumps.

Presently, anomalies in tissue like the breast are detected mostly by periodic palpation by the hand of a physician or radiographic mammography. To be effective, however, hand palpation must be frequent, particularly in older women in order to detect

tumors before they can metastasize. Unfortunately the subjective nature of hand palpation and the frequency required to make these examinations effective are often tremendous limitations that render palpation examinations ineffective due to convenience, availability, and cost. In addition, mammography is also troublesome due to the concern of accumulated radiation exposure from too frequent mammograms. It is also known that mammography, unlike palpation, can be limited as it may not detect very small tumors, particularly in the denser breast tissue of younger women.

In addition to anomalies, it is also very important that changes in tissue structures be detected and monitored over time. The problem, therefore, is how to detect minor changes in tissue. For example, hand palpation of tissue may not reveal very small changes and anomalies within breast tissue until the tissue changes are so large or the anomalies so prominent that they can be detected and no longer responsive to early treatment.

Another problem limiting the effectiveness of hand palpation is that it is not possible to record, retain and at a later time recall historical data of prior detected anomalies, including their location and the nature of the changes over time. This is particularly the case for soft anomalous tissue that is located further from the surface of the skin with diameters that are less than 10 mm. It is also known that anomalies deeper in the tissue of large breasts are particularly difficult to detect by hand palpation. Even if detected, it is often not possible to characterize the tissue or changes in the tissue due to the subjective nature and lack of standards for hand palpation which almost entirely depends on the skill and sensitivity of the examining physician.

Accordingly, the present invention address each of the aforementioned problems and urgent needs in the art for improved apparatus and methods for early detection of tissue anomalies and changes in tissue structures, particularly very small anomalies in breast tissue, as well as the urgent need to objectively determine tissue characteristics and produce, maintain, and compare tissue mapping and images of the tissue and its characteristics over time.

SUMMARY OF THE INVENTION

The present invention is an apparatus and method for detecting anomalies in human tissue. In one embodiment of the invention, the apparatus and method includes palpation by at least one palpation device for palpating tissue such as a human breast tissue and detection by at least one detector for detecting the time, distance traveled by, and the velocity of motion of the palpation probe. The apparatus and method includes measurement by a controller in communication with the palpation device and the detector for measuring a predetermined diagnostically relevant tissue characteristics from the probed breast tissue.

In one embodiment of the invention, the apparatus automatically scans, maps, and palpates an entire breast in a continuous manner, and compares adjacent tissue densities in order to detect changes in the physical characteristics of the breast tissue. Tissue density is measured across the entire breast and differentiated by means of relativistic or historic data in order to detect tissue changes and anomalies including their location and size. Further, the invention records, retains and recalls historical data of the detected anomalies and detected tissue characteristics for comparison and mapping of the data,

including anomaly location and changes over time. Although breast tissue is used as an example of the tissue under investigation throughout this disclosure, it is to be understood that any tissue structure can be palpated and characterized by this invention.

In another embodiment of the invention, the apparatus includes a platform on which a patient is positioned in a consistently similar manner each time the patient is tested. The platform is controlled by a location device such as an optical or video detector. A detection device such as a palpation probe is mounted on a carriage for movement in at least three directions adjacent to the patient. The location device continuously positions the patient so that the detection device can measure the tissue characteristics of the selected tissue under investigation.

The palpation device includes at least one probe or finger-like palpation end movable toward and away from the surface of the selected tissue in order to palpate the breast in the same general manner as a physician. The palpation device includes a probe that is maintained perpendicular to the selected tissue and movable across the entire surface of the selected tissue or beyond.

Information sensed by the palpation device is collected, stored and displayed in a manner that will show details of detected anomalies for comparison with historical data, and so that further testing, including automated biopsy and treatment, if required, can be performed. For example, a sampling device such as a biopsy needle or an aspiration device may be incorporated with the invention. Alternatively, the sampling device may also include devices such as an electromagnetic sensing device, temperature measuring device, or an ultrasound device. In addition, the invention may be used to treat a patient

by directing radiologic, chemotherapeutic treatments, or even surgical instruments that are directed by, or attached to the movable arm provided by, the invention.

Although the invention may be used to characterize breast tissue, it is understood that the invention may be used to characterize any tissue such as, but not limited to, the face, abdomen, thighs, and buttocks, which may be measured by palpation to measure and locate tissue structure such as subcutaneous fat. Further, detected regions of fat can be located and removed by the invention by a liposuction device that is directed by the invention. In addition, the invention may be used to palpate and detect lesions of the skin.

BRIEF DESCRIPTION OF THE DRAWINGS

For the purpose of illustrating the invention, there is shown in the drawings a form which is presently preferred; it being understood, however, that this invention is not limited to the precise arrangements and instrumentalities shown.

Figure 1 is an illustration of a detection device for detecting anomalies in human tissue according to the present invention.

Figure 2 is an illustration of a patient positioning platform for use with the detection device shown in Fig. 1.

Figure 3 is an illustration of a detection head and actuator according to the present invention.

Figure 4 and 4A illustrate a position and movement measurement device used with the detection head and actuator shown in Fig. 3.

Figure 5 is an illustration of a locator head assembly according to the present

invention.

Figure 6 is an illustration of a vertical positioning mechanism for use with a detection device.

Figures 7-10 illustrate alternate embodiments of a detection head according to the present invention.

Figure 11 illustrates a palpation tip for a detection head according to the present invention.

Figure 12 illustrates a detection head having a plurality of parallel palpation tips according to the present invention.

Figures 13a-13b illustrate an actuator with an encoder according to the present invention.

Figure 14 illustrates an optical locating head and detection head mounted to a carriage according to the present invention.

Figure 15 illustrates the internal components of an alternate embodiment of a locator head assembly according to the present invention.

Figure 16 illustrates a detection head and actuator having a sampling device according to the present invention.

Figure 17 illustrates an optical locating head and detection head having a sampling device mounted to a carriage according to the present invention.

Figures 18A-18C illustrate alternate embodiments of sampling devices according to the present invention.

DETAILED DESCRIPTION OF THE INVENTION

Referring now to the drawings, wherein like numerals indicate like elements, there is shown in FIG. 1 an illustration of one embodiment of an apparatus 10 for detecting anomalies in human tissue according to the present invention. In one aspect of the invention, the apparatus 10 includes a carriage (also referred to as a robot arm) 11 that is mounted at a proximal end to a horizontal support 12 for movement therealong, and a detector 14 (also referred to as a detection head) that is mounted at the distal end of the carriage 11. The detector is shown in more detail in FIG.s 3 and 4 and is used to detect the characteristics of tissue by palpation. A locator 16, for locating the position of a patient relative to some reference, is mounted to the carriage 11 for movement therewith. Data is produced by the palpation device and collected, stored and displayed in a manner that will capture details of the detected anomalies for comparison with historical data. The invention provides data about the tissue under investigation by means of an automated biopsy and treatment by means of surgical attachments for the delivery of radiologic, chemotherapeutic, or laproscopic surgery.

For example, the digital information can be received, stored, processed or displayed in a similar manner to existing medical devices such as a CAT scan or MRI.

In addition, the invention can produce multi-dimensional images that may be viewed on conventional computer monitors. Images may be produced using color to indicate areas of differing tissue density. These images may be further enhanced by combining tissue density information with tissue color and temperature information to detect and track even smaller tumors in discrete tissue areas.

Horizontal Movement

In one embodiment of the invention, the support structure of which is shown in detail in FIG. 6, the detector 14 is positioned over the patient and provided with horizontal movement by means of a horizontal support 12 that is mounted on a vertical support mechanism 18, allowing the horizontal support 12 to move in a vertical direction.

The horizontal support 12 includes a traveler 20 that rides on bearings 22 along rods or tubes 24 that are secured at their ends to end blocks 26,28. A lead screw 30 is driven by a drive motor 34 and extends between a pair of end blocks 26,28 and bearings 32. Lead screw 30 extends through correspondingly threaded openings 36 of the traveler 20 so that the traveler 20 will move to the right or left as the lead screw 30 is rotated in one direction or the other, and limit switches 37 are used to prevent over travel of the traveler 20. Guide rods 38 extend vertically through the end blocks 26,28 so that the horizontal support 12 can be moved vertically by means of a lead screw 40 that extends vertically through one end block 28.

The carriage 11 includes a base 42 secured to the traveler 20. A motor 44 within the base 42 rotates a screw 46 that is threaded into an intermediate body 48 to raise and lower the intermediate body 48 as the screw 46 is rotated one way or the other. A pair of guide rods 50 extend through a bracket 52 to guide movement of the intermediate body 48. A lower body 54 is secured to the intermediate body 48 for rotation relative thereto.

A motor 56 is mounted on the intermediate body 48 with the lower body 54 mounted on the motor shaft 58 for rotation with the shaft 58.

Vertical Movement

The detector 14 is positioned over the patient and provided with vertical movement by means of a mechanism for raising and lowering the entire carriage 11, as shown in FIG. 6. The carriage 11 is supported by a pair of vertical guide rods 38 that extend from a sturdy base 156 to a top plate 158. A pair of end blocks 26,28 support the horizontal support 12 and provide vertical movement therealong.

A motor 160 rotates a sturdy lead screw 40 threaded through a block 28. An upper limit switch 164 and a lower limit switch 166 prevent movement of the horizontal support 12 beyond desired limits. For a very strong, sturdy assembly, the base 156 will rest on the floor or a sub-floor so that the platform 67 could be positioned within the frame formed by the base 156, the top plate 158 and the guide rods 38.

Positioning Arm

An arm 61 is pivotally mounted at a pivot 62 on a bracket 64 that is mounted on the distal end of the lower body 54. A motor 60 on the lower body 54 drives a pulley 63 on the arm 61 through a jackshaft 65. Thus, the entire carriage 11 can be moved horizontally by the horizontal the support 12, and vertically by the vertical support 18.

The lower body 54 of the carriage 11 can be rotated 360°. The arm 61 carries the detector 14 which can be pivoted through at least 120°. The arm 61 can also carry and operate other devices such as, but not limited to, attachments for the delivery of acoustic, radiologic, chemotherapeutic treatments or laparoscopic surgery. The combination of movements just described, permit the detector 14 to be positioned in any desired position relative to any portion the surface of human body, particularly a breast.

Although a particular positioning arrangement of the detector 14 has been

described, it is understood that the invention can include any type of positioning system that will provided several degrees of freedom of movement for the detector 14 or other devices.

Position and Location System

In one embodiment of the invention, an investigation of a selected body part or region is started by positioning the patient on a platform (also referred to as a bed) 67 that is affixed to a position adjusting assembly 69 such as that shown in FIG. 2. The platform 67 is typically positioned below the detector 14 of FIG. 1. The platform 67 has a comfortably padded upper surface and a matrix board 66 with a location pattern 71, that is typically positioned adjacent to the shoulders of the patient 68.

The matrix board 66 and pattern 71 are used to maintain registration between the specific points of the patient's body under investigation and the acquired measured data. In addition, the matrix board 66 and pattern 71 are used to maintain registration between subsequent measurements taken at different times for the same patient 68.

For example, optical measuring means such as, but not limited to, a video camera, a fiducial reference target, or a laser location device can be used to locate the exact position of the patient or selected body parts such as arms, shoulders and neck relative to the matrix board 66 and its pattern 71 during an investigation.

In subsequent investigations, the patient 68 is positioned on the platform 67 at a later time, and the optical system, and with or without the aid of adaptive software techniques, the invention will correlate prior and presently collected location data measurement data with multiple prior measurements. Further, movement by the patient

68 that may introduce errors in the measured data can be corrected during the investigation by error correction techniques provided by the optical system. Although it is desirable that the patient 68 be placed in the same position for each investigation, it is not required since that the invention can correct for any change in position by means of position reference data collected during each periodic investigation.

Referring to FIG. 2, the underside of platform 67 includes conventional tubular bearings through which a pair of horizontal guide rods 70 pass. A central threaded rod 72, driven by a motor 76, engages end bearings 74. As the motor 76 rotates the platform 67 is moved right to left. The platform 67 is similarly moved up and down by means of a pair of guide rods 78 secured to end walls 80 of assembly 69 and driven by a motor 84 that rotates a threaded rod 82 which moves the platform 67 as desired.

The invention provides a means to control the position of the patient for consistent reinvestigation. This is accomplished by means of the platform 67 and a location device (also referred to as a sensor or a head) 16 which is shown in FIG. 5. The location device 16 provides accurate location information for positioning the patient 68 on the platform 67 or for correlating the data with subsequent or prior measurements by means of geometric translation which can be achieved by pattern recognition or reference to a fixed fiducial reference.

For example, a digital camera 134 may be used to produce a digitized image of the tissue under investigation. The image may then be compared by a computer system or technician to prior or subsequent images. A white light source 136 may also be used to produce a three dimensional image. As shown in FIG. 5, the light source 136 is

employed with an auto-focus system having a lens 138, and a lead screw 140 rotatable by a motor 142 and threaded through a lens mount bracket 144 for focusing a light spot on the surface of the tissue under investigation. The spot of light is moved transversely and focused at different depths along the tissue surface. Data of the focus position of the lens 138 is collected and used to produce a three dimensional image of the tissue surface.

In another aspect of the invention as shown in FIG. 5, a laser scanner 146 may be used to create a three-dimensional image. The laser scanner 146 includes a laser emitter 148 and a focusing system 150 for producing a focused laser spot on the surface of the tissue under investigation. For example, a laser operable in the range of 680-820 nm with a power level about 0.0095 should provide sufficient laser power to produce an image without damaging the tissue under investigation.

In all aspects of the invention, prior and subsequently collected image data can be used to translate position data of the tissue under investigation. This feature provides enhanced capabilities in the examination of anomalies in the tissue under investigation. For example, a three-dimensional image can be divided into a matrix of cubes or slices with geometric indicia (e.g., a cube might be identified as cube 2,4,9 on an x-y-z axis basis) and locations can be directly compared between the light spot image and the probe palpation locations.

Palpation Systems

One embodiment of the detector 14 according to the present invention is shown in FIG. 3. The detector 14 is shown with a removable connection 86 for attachment onto a rotatable arm 61. The detector 14 has a palpation probe housing 90 for supporting a

palpation probe or finger 92 and a sensor 94. The sensor 94 includes, but is not limited to, a device for sensing distance, acoustic waves, x-rays, MRI, color, and temperature. The sensor 94 may also be mounted to the detector's main housing 87. The palpation probe 92 is designed to simulate a physician's finger during a palpation investigation like that in a manual breast examination. In a preferred embodiment, the palpation probe 92 is composed of a disposable material, such as, but not limited to, glass or plastic.

Distance is measured by means of a sensor 94, which is an autofocus system like that used in cameras. The auto-focus system can provide precise data such as the distance between the breast surface and a known reference point within the sensor. In another aspect of the invention, a plurality of spaced range finders can be used to measure the angle with respect to the breast surface so that the orientation of the palpation probe 92 is maintained at a pre-determined angle such as, but not limited to a, perpendicular to the tissue under investigation.

Color is sensed by a color sensing device such as a photo-detection diode or spectrum detection sensor. In addition, a prism or diffraction grating for dispersing incoming light and refracting each color of light to an independent photoelectric sensor may also be used.

Referring to FIG. 3, one aspect of the invention the palpation probe 92 is secured to the distal end of a first shaft 100 which is slidably connected to the housing 90 and pivoted, at its proximal end, to the distal end of a first arm 102 at a pivot point 104. The first arm 102 is rotatable about an axis 106 that is centrally located along a second arm 98. The proximal end of the first arm 102 is pivotally connected to a drive shaft 108 at

a second pivot point 110. When the drive shaft 108 is moved axially by an actuator located within an actuator housing 112, which is shown in detail in FIG. 4, the first shaft 100 and the palpation probe 92 move a proportional distance in the opposite direction.

The motion of the palpation probe 92 is then measured to determine time, distance traveled, velocity, and resistance encountered by the probe 92 as it comes in contact with the tissue under investigation. For example, an optical reading device 126 having a laser source is located in a reader housing 114 for detecting movement of the palpation probe 92 by means of an optical encoded gradient 113 attached to the drive shaft 108. The parameters of time, distance traveled, and rate thereof, are used to determine a characteristic value of the tissue under investigation in response to the feedback resistance experienced by the palpation probe 92 when it is pressed against the tissue under investigation.

To further improve the accuracy of the measurements, a position error correction sensor 116 is used in cooperation with a position detection member 119 such as, but not limited to, an optical gradient, inertial displacement device or motion sensor, that is attached to the first shaft 100 to detect and correct positioning errors. The position error correction sensor 116 is used to correct movement and position errors of the components of the detector 14. Movement of the palpation probe is accomplished by the activation of magnetic coils 118, which are shown in detail in FIG. 4. Slight changes in position of the tissue under investigation like that caused by breathing, can be sensed by the palpation probe and a corresponding position correction signal can be sent to selected coils of the magnetic coils 118 to correct displacement errors.

In one embodiment of the invention, the palpation probe 92 is moved by a series of electromagnetic coils 118 that are arranged in a uniformly spaced relationship along a central tube 120. In a preferred configuration, the electromagnetic coils 118 may be formed as a continuous helix to form a solenoid. An end shaft 122 is axially secured to the proximal end of the drive shaft 108 and extends into a tube 120.

An end shaft 122 is formed from a magnetic material so that when the coils 118 are actuated sequentially, beginning with the coil adjacent to the end shaft 122, the magnetic forces in the coils 118 will pull the end shaft 122 into the tube 120. Alternately, the coils 118 are actuated individually in a sequence or by applying incrementally increasing voltages to the coils 118. The extension of the drive shaft 108 is controlled by the movement of the end shaft 122 which can be adjusted by a threaded mechanism 128. The maximum excursion of the drive shaft 108 is limited by a pin 130 extending from the drive shaft 108 and a pair of limit switches 132.

The magnetic force applied is sufficient to advance the palpation probe 92 to compress the tissue under investigation but not enough to cause discomfort or damage to the tissue. The time and distance the probe advances will be in proportion to the density of the tissue, resulting in less time and movement for dense tissue and more time and movement for less dense tissue.

In operation, a first coil 118 is actuated to move the palpation probe 92 a predetermined force, distance, time, or some combination thereof. The first coil 118 is energized in a step-wise fashion at about 250mv increments from 0 to 10 volts, and the change in force is about 10 grams per mm^2 per step. When the probe fails to move a

predetermined distance for a predetermined time, additional force is applied by means of a second coil 118. It is to be understood that additional coils similarly operated, can be added as required.

The resistance characteristic of the tissue under investigation is determined when the applied pressure, distance traveled or time of pressure reaches a predetermined value.

The parameters of force, distance or time are measured at the predetermined value and the parameter information is then transferred to information storage means and/or to a controller for processing, analysis, and the production of multi-dimensional images.

In one aspect of the invention, the palpation information including, but not limited to, distance, force, time, resistance, and characteristic value of the tissue under investigation, are obtained by encoding and transmitting the acquired palpation information. As shown in FIG. 4, a laser optic card 124 associated with the shaft 108 is read by a laser card reader 126 which transmits the encoded information to a storage device or the controller 17 for processing. The controller then processes the information as required for use by other devices or in a manner similar to CAT systems or equivalent devices.

An example of a laser card 124 that is to be used with the laser card reader 126 is shown in FIG. 4a. The card 124 has a series of reflecting areas 129 that are separated by non-reflective areas 131. The non-reflecting areas 131 of the card 124 can be light absorbing or transparent. A laser transmitter 133 directs a laser beam 135 against the patterned area of the laser card 124. When the laser beam 135 hits a reflecting area, reflected light is picked up by a receiver 137. As the card 124 is moved in a direction

transverse to the reader 126, the pattern of reflected pulses are counted to measure movement of the drive shaft 108 and the palpation probe 92. The reflecting areas can be as small as about 0.001 mm for more precise measurements of the motion of the palpation probe 92. Although only laser illumination has been discussed, it is to be understood that any form of illumination can be applied including, but not limited to, visible, infrared, or ultraviolet light, which may, or may not, be coherent, focused, columnated or diffused.

Palpation Actuators and Probes

In another aspect of the invention, a palpation detector for detecting changes in density of tissue is shown in FIG. 7. A permanent magnet 200 is mounted on a non-magnetic rod 202 that is movable along the axis of the rod centerline. Suitable guides 204 such as rollers, ball bearings, a sleeve or the like are provided for smooth, low resistance, axial movement of the rod 202. The permanent magnet 200 is proximate to an electromagnetic coil head 206 mounted on a shaft 207 and fixed to a housing 208. The permanent magnet 200 and the electromagnet head 206 have common poles while the rod 202 has an opposing pole 210. Electromagnet head 206 is powered by any suitable number of powered coils 212 that are connected at a terminal 214 to a power source by supply wires 216. The magnets 200, 206 having common poles will oppose each other pushing the magnets 200, 206 apart when the electromagnet coils 212 are activated. The intensity of the opposing force is adjusted by the number of coils 212 and the level of power applied thereto.

A palpation probe tip 218 is shown in FIG. 11, according to the present invention.

The palpation probe tip 218 is mounted on the distal end of the rod 202 which is brought into contact with (or to a predetermined distance from) the tissue under investigation such as a breast surface by the carriage 11. The coil 212 is energized to increase the field around a shaft 207 to increase the field at the electromagnetic head 206 in order to force the permanent magnet 200 further away from the electromagnetic head 206, which moves the palpation probe tip 218 against the tissue. The tissue is depressed at the point of contact which transfers the tissue's elasticity characteristic in the form of a back pressure through the probe tip 218 and rod 202 toward the coil head 206.

The amount of back pressure applied including variations thereof are measured by recording instrumentation associated with the processor 17. It is to be understood that this pressure measurement system can be incorporated with any palpation device disclosed herein. Additional embodiments of palpation detection and actuator devices are shown in FIG.s 8 - 14.

The detection and actuator device shown in FIG. 8 includes a permanent magnet 222 that is mounted at one end to an actuator rod 224 which is supported by a slidable sleeve 226 that is mounted on a housing 228. A tip 218 of the sort shown in FIG. 11 is secured to the other end of rod 224. A second permanent magnet 230 is mounted on a holder 231 that is coaxial with the rod 224. The permanent magnets 222,230 are selected with common poles (north to north or south to south.) The holder 231 is supported on a disk 232 that is slidable within the housing 234 and coaxial with the rod 224. A sleeve 236 is preferably mounted on the holder 231 to aid in guiding the movement of the rod 224.

FIG. 11 shows a preferred embodiment of a palpation tip configuration 218. The tip configuration 218 includes a rounded endpiece 254 for contact with the tissue under investigation. Any suitable material may be used that can be inexpensively cleaned and made safely disposable is preferred. An end isolator 256, made up of an electrically insulating material is used to prevent static electricity discharge of the tissue. A core member 258 connects the endpiece 254 to a base 260 which is secured in any suitable manner, such as threads, to the rod 224.

In operation, the detector 14 is moved as discussed above to bring the palpation tip 218 into proximity with a selected location along the tissue under investigation. When the palpation tip 218 is initially brought into proximity to the breast surface, gravity causes the rod 224 and the permanent magnets 222 to move apart. A motor 238 mounted in a housing 234 drives a lead screw 240 which is threaded through a corresponding female thread 241 in a disk 232. The motor 238 may be any suitable motor, such as a low rpm DC motor or a stepper motor. Rotation of the lead screw 240 will move magnet 230 towards magnet 222 decreasing the intermagnet gap until the tissue resistance returns the intermagnet gap to a predetermined distance. The displacement of the holder 231 and the disk 232 is related to the tissue density characteristics of the tissue at the contact point. A sensor 242 counts the revolutions of the motor 238 to measure the corresponding degree of movement of the palpation tip 218 into the tissue.

Conventional safety sensors 244 may be provided to limit maximum movement of disk 232 (and movement of tip 218 in accordance with disk position) to prevent

damage to the breast. As mentioned above, the magnetic field between the magnets 222, 230 will act as a resilient mount for the palpation probe tip 218, limiting any damage or injury should the tip strike a breast or other surface.

FIG. 9 shows another embodiment of a detector 14 having a pair of housings 228, 234, an actuator rod 224, sleeves 226, 236, a palpation tip 218, a holder 231, a disk 232, a motor 238, and sensors 242, 244. Instead of spaced permanent magnets 222, 230 a spring 248 is fastened between the proximal end of the rod 224 and the holder 231. The spring 248 is selected to provide a bias to the two juxtaposed ends of the rod 224 and the holder 231 to a particular, predetermined spacing. When the detector 14 is positioned over the tissue the palpation tip 218 extends downwardly under the force of gravity. The motor 238 rotates to move the disk 232 and holder 231 toward the rod 224 until the gap between the distal end of the holder 231 and the proximal end of the rod 224 is at the original predetermined distance. The total movement of the holder 231 is indicated by the number of revolutions of the lead screw 240 as measured by the counting sensor 242, which is indicative of the desired tissue characteristic.

Another aspect of a detector 14 is shown in FIG. 10 having a gas 250 interface that is enclosed within a sleeve 236 at the proximal end of a rod 224. The sleeve 236 fits over the rod 224 in a sealing arrangement to prevent the pressurized gas 250 from escaping. Any suitable conventional seals may be used between the rod 224 and the sleeve 236.

The axial force applied to the rod 224 will change the gas pressure within the sleeve 236 which will be measured by a pressure sensor. When placed in contact with

the tissue under investigation, the contact pressure is sensed 252 by the amount of pressure applied to the gas by the palpation probe 218. Pressure in the sleeve is adjusted by the rotation of the motor 238 which is counted by sensor 242. The amount of pressure applied by the rotation of the motor 238 is proportional to the desired tissue characteristic such as hardness and density.

FIG. 12 shows another detector 14 having a plurality of palpation probe tips 218 that are arranged in a parallel array and mounted on a corresponding number of actuator rods 262 for axial movement. In one aspect of the detector 14, a plurality of offset extension connectors 264 made of inflexible cables are used to transmit motion by means of transducers 266 that are connected to the output ends of the rods 262. An optical encoder and reader system 268 is incorporated to measure the movement of each palpation tip 218 during palpation of the tissue under investigation.

FIG.s 13a and 13b show two embodiments of the encoder and reader system 268 having a plurality of detectors 276 and encoder cards (strips) 272. The encoder system 268 includes an encoder slide 270 that is secured to the rod 224. The encoder slide 270 is secured to any suitable part of the rod 224 or to the palpation tip 218, as desired. The encoder slide 270 is transparent and includes a strip 272 with reflective dots 274 (or, in the alternative transparent dots in an otherwise opaque strip 272).

Decoder sensors 276 mounted on a housing 278 are provided on opposite sides of the encoder slide 270 and secured to the housing 278 by any suitable mounting means. The decoder sensors 276 are optical or laser sensors having light emitters of the sort used to read compact disks. The dots 274 are reflective particularly against a transparent

background which causes light to pass between the pair of light transmitting decoder sensors 276. As the encoder slide 270 is moved, light from the emitters is either reflected by the reflective dots 274 or transmitted through the disk and onto the opposite sensor 276.

Accordingly, the detected light indicates movement of the slide and the number of pulses of light received which are used to measure the distance of movement of the rod 224 and the palpation tip 218. Alternatively, when the dots 274 are transparent against an opaque background, light pulses received at the detector decoder sensor 276 will indicate the distance of movement of the rod 224 and the palpation tip 218. FIG. 14 shows another embodiment of the detector 14 in which the optical locating head 16 and detector 14 are both mounted at the end of the arm 61 on carriage 11.

FIG. 15 shows and optical locator 16 having a motor housing 282 in combination with a detector 16. A lens enclosure 284 is secured to the motor housing 282 after precise positioning during manufacture of the assembly. A lens assembly 286 is slidably mounted within lens enclosure 284 for axial movement relative thereto. A motor 288 is mounted within motor housing 282 and drives a lead screw 290 which is threaded through a nut 292 secured to lens assembly 286 to move the lens assembly 286 axially within lens enclosure 284.

Two laser beam positioning enclosures 294 are mounted on opposite sides of motor housing 282. Each enclosure 294 contains a pre-focused conventional (typically 680 to 850 nanometer) laser diode and light sensor 296. A prism 297 refracts light from a laser diode of the light sensor 296 toward the tissue being examined. Light reflected

from the tissue surface passes back through the prism 297 to the sensor 296. The sensed returned light will be at a maximum when the beam from the beam generated by the sensor 296 is 90° incident to the tissue surface. The mechanism described above for moving a palpation tip 218 in three dimensions can thus adjust the tip orientation to provide palpation at 90° to the breast surface.

A motor 300 in each laser beam positioning enclosure 294 drives a lead screw 302 that engages an arcuate gear sector 304 to rotate each sensor 296 and prism 297 about the center of rotation of gear sector 304. The laser diode within sensor 296 generates a laser beam that produces a red dot on the tissue being examined. A conventional sensor 306 within each enclosure 294 counts rotation of the lead screw 302 and is calibrated to indicate the exact distance to the surface upon which the dot appears when the beam is at 90° to the surface. The system computer then can conventionally calculate a three dimensional image of the tissue surface from a number of these angle readings.

Lens assembly 286, in conjunction with a light sensor 308, a pre-focused sensor lens 310 and lenses 312 operate in the same manner as a camera automatic focusing systems to bring the tissue surface into sharp optical focus by rotating the lead screw 290 as necessary. A position sensor 313 counts rotation of the lead screw 290 to provide position information to the processor 17 or some other system such as a computer. As the optical locator 16 moves and focuses on the tissue, the palpation detector 14 is brought into contact with the tissue surface.

Extreme position sensors 314 are preferably provided to sense movement of the

lens enclosure 284 to the ends of its desired range of movement and prevent damage which might be caused by movement outside the selected range. Sensors 314 may be conventional sensors, such as electro-optical or pressure switches, which can turn off motor 288.

Multi-dimensional Imaging

In operation, either of the locator 16 embodiments as shown in FIG. 5 or 15 can be conventionally programmed to map an entire breast and associated tissue step by step.

The horizontal and vertical (X and Y) movement of the robot arm (carriage) 11 position the location device 16 at selected points across the tissue under investigation. The focusing mechanism within the motor housing 282 and the lens enclosure 284 will continually focus the sensor 308 to provide the necessary Z direction alignment. The position sensor 313 will count the revolution of the motor 288 while the motor is bringing the lens assembly 286 to the point of focus to continuously provide lens position information.

Once the locator 16 has visited all desired points of the tissue and a calculation is made of the distance from every desired point, the processor 17 generates a multi-dimensional image (two or three dimensions) of the tissue under investigation.

For example, during the palpation of a breast, the locator 16 verifies the location being palpated and can automatically compensate for breast movement as the patient breathes. In addition, a map of the breast is produced by a video camera 316 mounted with the locator 16 as shown in FIG. 14. Other types of mapping can be produced by means of the distance traveled by the palpation probe 92, the velocity of travel of the

palpation probe 92, and the time of palpation at each contact point. For example, velocity data may be used, preferably in conjunction with the distance traveled and time data, to calculate the breast tissue density at each palpation point. Thus, the apparatus of this invention will provide an accurate map of the breast as well as detect tissue density anomalies, and provide the ability to accurately reexamine the breast from time to time to monitor any changes in breast density anomalies.

Sampling Devices

In addition, referring to the alternative embodiments illustrated in Figures 16 and 17, a sampling device 400 is provided to further examine the identified regions of tissue density anomalies in order to determine the predetermined tissue characteristics and regions such as, but not limited to, skin, fat, muscle, and abnormal tissue such as cancer.

The sampling device 400 is connected to a detector 14 that is in communication with the processor 17. The sampling device 400 may be either an invasive or non-invasive device 402 (Figure 18a), such as but not limited to a needle, an aspirator, coring device, ultrasound device, temperature device, electromagnetic sensing device, or an impedance measurement device or some combination thereof. The sampling device 400 is positioned by the processor 17 at predetermined locations of the tissue under investigation. By means of three dimensional mapping produced from the tissue density data, the sampling devices may be more effectively employed to obtain additional data or even tissue samples from the tissue under investigation.

Other examples of sampling devices that may be incorporated with the invention are shown in FIG.s 18a - 18c and include a biopsy needle and anesthetic delivery device,

406, a multi-electrode sensor array 404 for examining detected tissue anomalies, a T-Scan 2000 manufactured by TransScan Research and Development Ltd. for detecting low-level electric currents and impedance to produce a real-time image of the electrical distribution within the breast, an ultrasound device, a temperature measuring device, or a liposuction device 408.

While certain specific relationships, materials and other parameters have been detailed in the above description of preferred embodiments, those can be varied, where suitable, with similar results. In particular, application to assess other parts of the body is possible, such as, but not limited to, the face, abdomen, thighs, buttocks, etc. In these regions as well as the breast, the apparatus and method of the current invention may be used for the mapping of subcutaneous fat. Having created such a map of fat deposits, the invasive sampling device as discussed above may be used for the removal of fat. In addition, the apparatus and method of the current invention may be applied to assessing the cancerous state of skin lesions.

These and other advantages of the present invention will be apparent to those skilled in the art from the foregoing specification. Accordingly, it will be recognized by those skilled in the art that changes or modifications may be made to the above-described embodiments without departing from the broad inventive concepts of the invention. It should therefore be understood that this invention is not limited to the particular embodiments described herein, but is intended to include all changes and modifications that are within the scope and spirit of the invention as set forth in the claims.

CLAIMS

What is claimed is:

1. An apparatus for detecting anomalies in tissue, the apparatus comprising:
at least one palpation probe for palpating tissue;
at least one detector for detecting the distance traveled by and the velocity
of motion of the palpation probe as it palpates the tissue; and
a controller in communication with the palpation probe and the detector
for measuring a characteristic value of the probed tissue.
2. The apparatus according to claim 1 wherein the palpation probe is
operably connected with an electro-magnetic or electro-mechanical actuator.
3. The apparatus according to claim 1 wherein the detector includes an
optical encoder or a magnetic encoder.
4. The apparatus according to claim 1 including at least one sensor for
mapping the surface of the tissue.
5. The apparatus according to claim 1 wherein the controller produces a
dimensional mapping of the surface of the tissue.
6. The apparatus according to claim 4 wherein the at least one sensor
includes a camera, an autofocus system, a rangefinder, an acoustic sensor, or an optical
sensor.
7. The apparatus according to claim 4 wherein the at least one sensor

determines the distance from the palpation probe to the surface of the tissue.

8. The apparatus according to claim 4 wherein the at least one sensor determines the angle between the longitudinal axis of the palpation probe and the surface of the tissue.

9. The apparatus according to claim 1 including a second detector for measuring the color or temperature, or both, of the tissue.

10. The apparatus according to claim 1 wherein the controller produces a signal causing the actuator to move the palpation probe a distance, with a force, or for a time that is detected, or some combination thereof, against the surface of the tissue.

11. The apparatus according to claim 10 wherein the controller determines a characteristic value for the probed tissue from the detected distance, force, or time, or some combination thereof, traveled by the probe.

12. The apparatus according to claim 1 wherein the controller determines a characteristic value for the probed tissue from the detected distance traveled by the probe.

13. The apparatus according to claim 1 wherein the controller determines a characteristic value for the probed tissue from the detected distance traveled by the probe relative to a predetermined distance or time.

14. The apparatus according to claim 1 wherein the controller positions the palpation probe at a predetermined location against the tissue.

15. The apparatus according to claim 1 wherein the controller positions the

longitudinal axis of the palpation probe substantially perpendicular to the surface of the tissue.

16. The apparatus according to claim 1 wherein the controller positions the palpation probe at a series of predetermined locations about the tissue.

17. The apparatus according to claim 16 wherein the series of predetermined locations encompasses the entire tissue area under investigation.

18. The apparatus according to claim 16 wherein the controller actuates the palpation probe at each location, and stores in a memory the location of the palpation probe, the detected distance, the velocity motion, or a characteristic value of the tissue, or some combination thereof.

19. The apparatus according to claim 18 wherein the controller creates a multi-dimensional model of the probed tissue using the characteristic value of the tissue.

20. The apparatus according to claim 18 wherein the controller determines a boundary using the characteristic value of the tissue.

21. The apparatus according to claim 1 including a tissue sampling device for obtaining a sample of the tissue.

22. The apparatus according to claim 21 wherein the sampling device is an invasive, or non-invasive device, or both.

23. The apparatus according to claim 21 wherein the sampling device is a needle, aspirator, coring device, ultrasound device, temperature sensing device, electromagnetic sensing device, or an impedance measurement device.

24. The apparatus according to claim 21 comprising an anesthetic delivery device to anesthetize an area proximate to the sampled tissue.

25. The apparatus according to claim 20 wherein the controller is in communication with the sampling device.

26. The apparatus according to claim 20 wherein the controller positions the sampling device at a preselected region of the tissue.

27. An apparatus for detecting differences in breast tissue, the apparatus comprising:

- a palpation probe for palpating breast tissue;

- a detector for detecting the distance traveled by or the velocity of motion of the palpation probe; and

- a controller in communication with the palpation probe and the detector, the controller determining a breast tissue value for the probed breast tissue from the detected distance or velocity of motion.

28. The apparatus according to claim 27 wherein the palpation probe is operably connected with a solenoid.

29. The apparatus according to claim 27 wherein the controller positions the palpation probe at a predetermined location against the breast tissue .

30. The apparatus according to claim 27 wherein the controller applies a predetermined voltage to the solenoid to move the shaft a distance or speed determined by the resistance of the breast tissue .

31. The apparatus according to claim 27 wherein the detector includes an optical encoder or a magnetic encoder.

32. The apparatus according to claim 27 wherein the movement of the probe is detected by an encoding device.

33. The apparatus according to claim 32 wherein the encoding device is an optical encoder or a magnetic encoder.

34. An apparatus for detecting differences in breast tissue, the apparatus comprising:

- a detection device having a palpation probe for palpating breast tissue and a detector for detecting the distance traveled by and the velocity of motion of the palpation probe;

- a location sensor for detecting the location of the breast tissue for producing an image map of the breast;

- a controller in communication with the detection head and the location sensor, the controller positioning the palpation probe at a predetermined location along the breast tissue and directing the palpation probe against the breast tissue; and

- a memory device for storing the distance traveled and velocity of motion of the probed breast tissue.

35. The apparatus of claim 34 wherein the location sensor includes an optical sensor.

36. The apparatus of claim 34 wherein the controller includes a microprocessor.

37. The apparatus of claim 34 wherein the location sensor is incorporated with the detection device.

38. The apparatus of claim 34 including a processor for determining a breast tissue value for the probed breast tissue from the detected distance and velocity of motion of the palpation probe for producing a map of the breast tissue values.

39. The apparatus of claim 34 wherein the detection device includes a plurality of palpation probes.

40. An apparatus for detecting differences in breast tissue, the apparatus comprising a detection head having at least one palpation probe for palpating the breast tissue of a patient, and at least one detector for detecting the distance traveled by, or the velocity of motion of, or the time of motion of, said at least one palpation probe.

41. The apparatus of claim 40 including a location device having at least one sensor for determining the location of the breast tissue of the patient, the at least one sensor for mapping the surface of the breast tissue.

42. The apparatus of claim 41a including a controller in communication with the detection head and the location head for positioning the palpation probe at a predetermined location against the breast tissue and directing the palpation probe against the breast tissue.

43. The apparatus of claim 42 including a memory for storing the detected distance and velocity motion for the probed breast tissue.

44. The apparatus of claim 43 including a data processor for determining a breast tissue value for the probed breast tissue from the detected distance and velocity of

motion of the palpation probe.

45. The apparatus of claim 44 including a breast tissue sampling device for sampling the breast tissue.

46. A method for detecting differences in breast tissue, the method comprising the steps of:

- palpating the breast tissue of a patient with a palpation probe;
- detecting a distance traveled by, or a velocity of motion of, or a time in motion of, the palpation probe; and
- determining a breast tissue value for the probed breast tissue from the detected distance traveled by, or the velocity of motion of, or the time in motion.

47. The method according to claim 46 wherein the palpation probe is moved incrementally.

48. A method for detecting differences in breast tissue, the method comprising the steps of:

- (a) positioning a palpation probe at a predetermined location against the breast tissue of a patient;
- (b) actuating the palpation probe to move with a predetermined force against the breast tissue;
- (c) detecting the distance traveled by and the velocity of motion of the palpation probe;
- (d) determining a characteristic value for the probed breast tissue from at least one of the detected distance traveled, or the velocity of motion, or both; and
- (e) storing the palpation probe location, detected distance, velocity of motion, or breast tissue value, or a combination thereof, in a memory.

49. The method of claim 48 which comprises repeating steps (c) through (e).

50. The method of claim 48 which comprises the step of positioning the palpation probe at an alternate predetermined location against the breast tissue and repeating steps of claim 48.

51. A method for mapping differences in breast tissue values, the method comprising the steps of:

- (a) positioning a palpation probe at a predetermined location against the breast tissue of a patient;
- (b) orienting a longitudinal axis of the palpation probe at substantially normal incidence to the surface of the breast tissue;
- (c) actuating the palpation probe to move with a predetermined force against the breast tissue;
- (d) detecting the distance traveled by and the velocity of motion of the palpation probe;
- (e) determining a breast tissue value for the probed breast tissue from at least one of the detected distance traveled or velocity of motion; and
- (f) storing palpation probe location, detected distance, velocity of motion, and breast tissue value in a memory.

52. The method of claim 51 which comprises repeating steps (c) through (f).

53. The method of claim 51 which comprises the step of positioning the palpation probe at an alternate predetermined location against the breast tissue and repeating the steps of claim 51.

54. The method of claim 51 which comprises the step of identifying a region

of breast tissue having a predetermined characteristic value.

55. The method of claim 54 which comprises the step of sampling the region of breast tissue with a sampling device.

56. An apparatus for detecting differences in body tissue, the apparatus comprising:

at least one palpation probe for palpating body tissue;

at least one detector for detecting the distance traveled by, or the velocity of motion of the palpation probe; and

a controller in communication with the palpation probe and the at least one detector for measuring a characteristic value of the probed body tissue.

57. The apparatus of claim 56 wherein the controller determines whether the body tissue detected is skin, subcutaneous fatty tissue, benign tissue, or cancerous tissue, or a combination thereof.

58. The apparatus of claim 56 wherein the body tissue detected is located on the face, abdomen, thigh, buttocks, or body.

59. The apparatus according to claim 56 wherein the palpation probe is operably connected to an electro-magnetic or a electro-mechanical actuator.

60. The apparatus according to claim 56 wherein the detector is an optical encoder or a magnetic encoder.

61. The apparatus according to claim 56 including at least one sensor for mapping the surface of the body tissue.

62. The apparatus according to claim 56 wherein the controller produces multi-dimensional mapping of the surface of the body tissue.

63. The apparatus according to claim 61 wherein the at least one sensor includes a camera, an autofocus system, a rangefinder, an acoustic sensor, or an optical sensor.

64. The apparatus according to claim 61 wherein the at least one sensor determines the distance from the palpation probe to the body tissue.

65. The apparatus according to claim 61 wherein the at least one sensor determines the angle between the longitudinal axis of the palpation probe and surface of the probed body tissue.

66. The apparatus according to claim 56 including a second detector for measuring the color or the temperature of the probed body tissue.

67. The apparatus according to claim 56 wherein the controller delivers a signal to the actuator to move the palpation probe with a predetermined force against the body tissue.

68. The apparatus according to claim 56 wherein the controller determines a characteristic value for the probed body tissue from the detected distance relative to a predetermined distance.

69. The apparatus according to claim 56 wherein the controller positions the palpation probe at a predetermined location against the body tissue.

70. The apparatus according to claim 56 wherein the controller positions a

longitudinal axis of the palpation probe substantially perpendicular to the surface of the body tissue.

71. The apparatus according to claim 56 wherein the controller positions the palpation probe at a series of predetermined locations across the body tissue.

72. The apparatus according to claim 71 wherein the series of predetermined locations encompasses the entire body area under investigation.

73. The apparatus according to claim 71 wherein the controller actuates the palpation probe at each location and stores in a memory the location of the palpation probe, the detected distance, the velocity motion, or a characteristic value for the probed body tissue, or a combination thereof.

74. The apparatus according to claim 73 wherein the controller produces a multi-dimensional model of the characteristic values of the probed body tissue.

75. The apparatus according to claim 73 wherein the controller determines a characteristic value for the probed body tissue.

76. The apparatus according to claim 56 including a body tissue sampling device for determining the cancerous state of the sampled body tissue.

77. The apparatus according to claim 76 wherein the sampling device is an invasive device.

78. The apparatus according to claim 76 wherein the sampling device is a non-invasive device.

79. The apparatus according to claim 76 wherein the sampling device is a biopsy device.

80. The apparatus according to claim 79 wherein the biopsy device is an aspiration device.

81. The apparatus according to claim 79 wherein the biopsy device removes a tissue sample.

82. The apparatus according to claim 81 wherein the biopsy device comprises a needle.

83. The apparatus according to claim 76 wherein the sampling device is an ultrasound device.

84. The apparatus according to claim 76 wherein the sampling device is a temperature measurement device.

85. The apparatus according to claim 76 wherein the sampling device is an electromagnetic sensing device.

86. The apparatus according to claim 85 wherein the sensing device comprises a sensor array.

87. The apparatus according to claim 86 wherein the sensor array measures low-level electric currents to produce an image of the electrical impedance within the body.

88. The apparatus according to claim 56 including an anesthetic delivery

device to anesthetize an area proximate to the sampled body tissue.

89. The apparatus according to claim 56 wherein the controller is in communication with the sampling device.

90. The apparatus according to claim 56 wherein the controller determines the boundary of the detected characteristic values of body tissue.

91. The apparatus according to claim 73 wherein the controller determines whether the body tissue detected is skin, subcutaneous fatty tissue, benign tissue, or cancerous tissue, or a combination thereof.

92. The apparatus according to claim 56 including a liposuction device.

93. A method for mapping differences in characteristic values of body tissue, the method comprising the steps of:

- (a) positioning a palpation probe at a predetermined location against the body tissue of a patient;
- (b) actuating the palpation probe with an actuator to move with a predetermined force against the body tissue;
- (c) detecting the time traveled by, distance traveled by, or the velocity of motion of, the palpation probe;
- (d) determining a characteristic value of body tissue for the probed body tissue from at least one of the detected time traveled, distance traveled, or velocity of motion; and
- (e) storing palpation probe location, detected distance, velocity of motion, or the characteristic value of tissue, or any combination thereof, in a memory.

94. The method of claim 93 wherein the characteristic value of body tissue determined in step (d) corresponds to a predetermined characteristic value of tissue associated with a predetermined region of the body.

95. The method of claim 94 wherein the predetermined characteristic value of tissue corresponds to skin, subcutaneous fatty tissue, benign tissue, or cancerous tissue.

96. The method of claim 94 wherein the predetermined region of the body corresponds to the face, abdomen, thigh, or buttocks.

97. The method of claim 93 which comprises the step of removing tissue having a predetermined characteristic value.

98. The method of claim 97 wherein the tissue removed has a predetermined characteristic value corresponding to skin, subcutaneous fatty tissue, benign tissue, or cancerous tissue.

99. The method of claim 97 wherein the tissue is removed by means of a laser, mechanical, chemical, or cryogenic device.

100. A method for mapping differences in characteristic values of body tissue, the method comprising the steps of:

- (a) positioning a palpation probe at a predetermined location against the body tissue of a patient;
- (b) actuating the palpation probe with an actuator to move with a predetermined force against the body tissue; and
- (c) detecting the time traveled by, distance traveled by, or the velocity of motion of, the palpation probe.

101. The method of claim 100 including the step of determining a characteristic value of body tissue for the probed body tissue from at least one of the detected time traveled, distance traveled, or velocity of motion.

102. The method of claim 101 including the step of storing palpation probe location, detected distance, velocity of motion, or the characteristic value of tissue, or any combination thereof, in a memory.

103. The apparatus according to claim 4 wherein one sensor includes a digital camera and grid to establish investigation coordinates for use in comparing measurements made at some other time.

104. The apparatus according to claim 34 wherein the sensor includes a digital camera and grid to establish investigation coordinates for use in comparing measurements made at some other time.

105. The apparatus according to claim 2 wherein the palpation probe includes an end isolator composed of an electrically insulating material.

APPARATUS AND METHOD FOR DETECTING ANOMALIES IN HUMAN TISSUE

ABSTRACT

This invention relates to apparatus and methods for detecting human tissues, and in particular for detecting very small anomalies such as tumors in a human breast. The invention includes tissue mapping, the detection of tissue anomalies, generating an electrical signal and graphical data corresponding thereto, and automated tissue imaging and sampling for characterizing detected tissue anomalies.

The invention includes apparatus and methods for detecting anomalies such as lumps and subcutaneous fat in mammal tissue by means of computer-controlled palpation. The apparatus and methods includes detection device capable of movement in three dimensions over a selected portion of the body. The detection device includes a palpation probe that is brought into contact across the selected portion of the body, palpating each selected portion in a sequence of movements to measure relative differences in tissue density. The apparatus also includes a scanning device for mapping the selected portion of the body, detecting tissue color, or detecting temperature. The apparatus also includes a locator device for positioning the detector or scanning device for accuracy and repeatability of palpation and scanning over a series of periodic investigations. The apparatus also includes a sampling device for obtaining tissue samples from the selected tissue that may be used to characterize the cells of the selected tissue.

ELEMENT LIST

10	invention	82	Central threaded rod
11	carriage	84	motor
12	horizontal support	85	posts
14	detection head	87	main housing
16	locator head	88	motor
17	computer center	90	detector housing
18	vertical support mechanism	92	palpation probe
20	traveler	94	sensor
22	bearings	96,98	arms
24	rods or tubes	95	rangefinder
26,28	end blocks	100	shaft
30	lead screw	102	arm
32	bearings	104	pivot point
36	walls	106	axis
37	limit switches	108	shaft
38	guide rods	110	pivot point
40	lead screw	112	actuator housing
42	base	114	reader housing
44	motor	116	correction sensor
48	intermediate body	118	magnetic coils
50	guide rods	119	member
52	brackets	120	Central 2
54	lower body	122	and shaft
56	motor	123	sleeve
61	arm	124	laser optic card
62	platform	126	card reader
56	motor shaft	128	adjustment mechanism
60	motor	129	reflecting areas
61	arm	130	pin
62	pulley	131	nonreflecting areas
64	check shaft	132	limit switches
62	platform	133	laser
64	position adjusting assembly	134	digital camera
66	matrix boards	136	light source
68	person	135	laser beam
70	horizontal guide rods	137	laser card
72	threaded rod	137	receiver
74	end bearings	138	lens
76	nut assembly	140	lead screw
78	guide rods	142	motor
80	end walls	144	bracket

146	laser scanner	248	spring
148	laser emitter	250	gas
150	focusing system	254	end piece
152	window	256	end isolator
154	window	258	core member
156	base	260	base
158	Plate	262	rods
160	motor	264	connectors
162	lead screw	266	systems
164	upper limit switch	268	of assembly
166	lower limit switch	270	slide
200	magnet	272	strip
202	non-magnetic rod	274	dots
204	guides	276	sensors
206	coil head	278	housing
207	shaft	284	lens enclosure
208	housing	288	motor
210	south pole	286	lens assembly
212	powered coils	290	lead screw
214	terminal	294	laser beam positioning enclosure
216	wires	296	laser diode unit
218	palpation tip	296	diode
222	magnet	297	prism
224	actuator rods	298	beam
226	sleeve	299	center of rotation
228	housing	300	motor
228	rod	302	screw
229	tip	304	gear sector
230	magnet	310	sensor lens
231	Holder	312	lenses
232	disk	313	sensor
234	housing	314	position sensors
236	sleeve	316	video camera
238	motor		
244	safety sensors		

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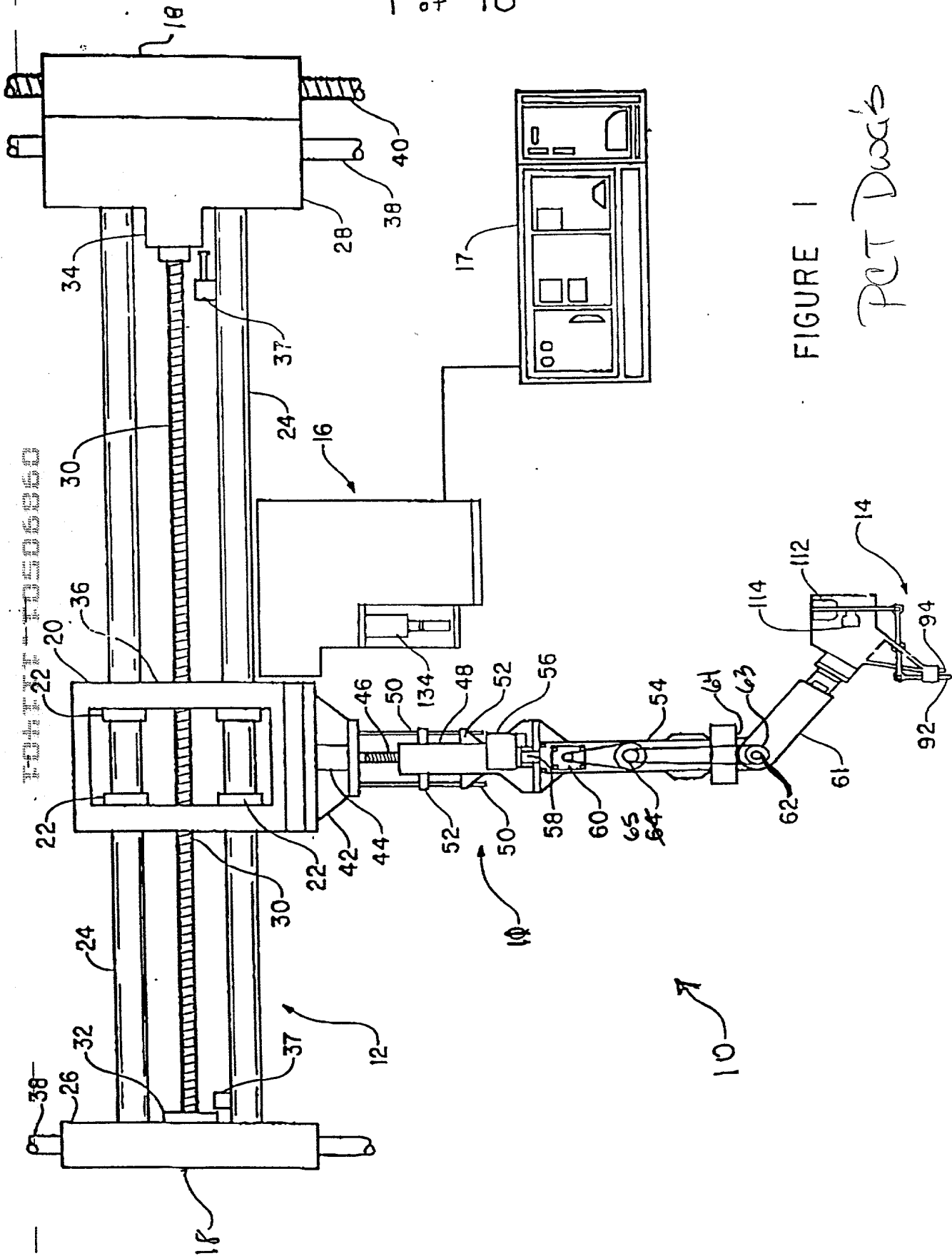


FIGURE 1

PET Dog's

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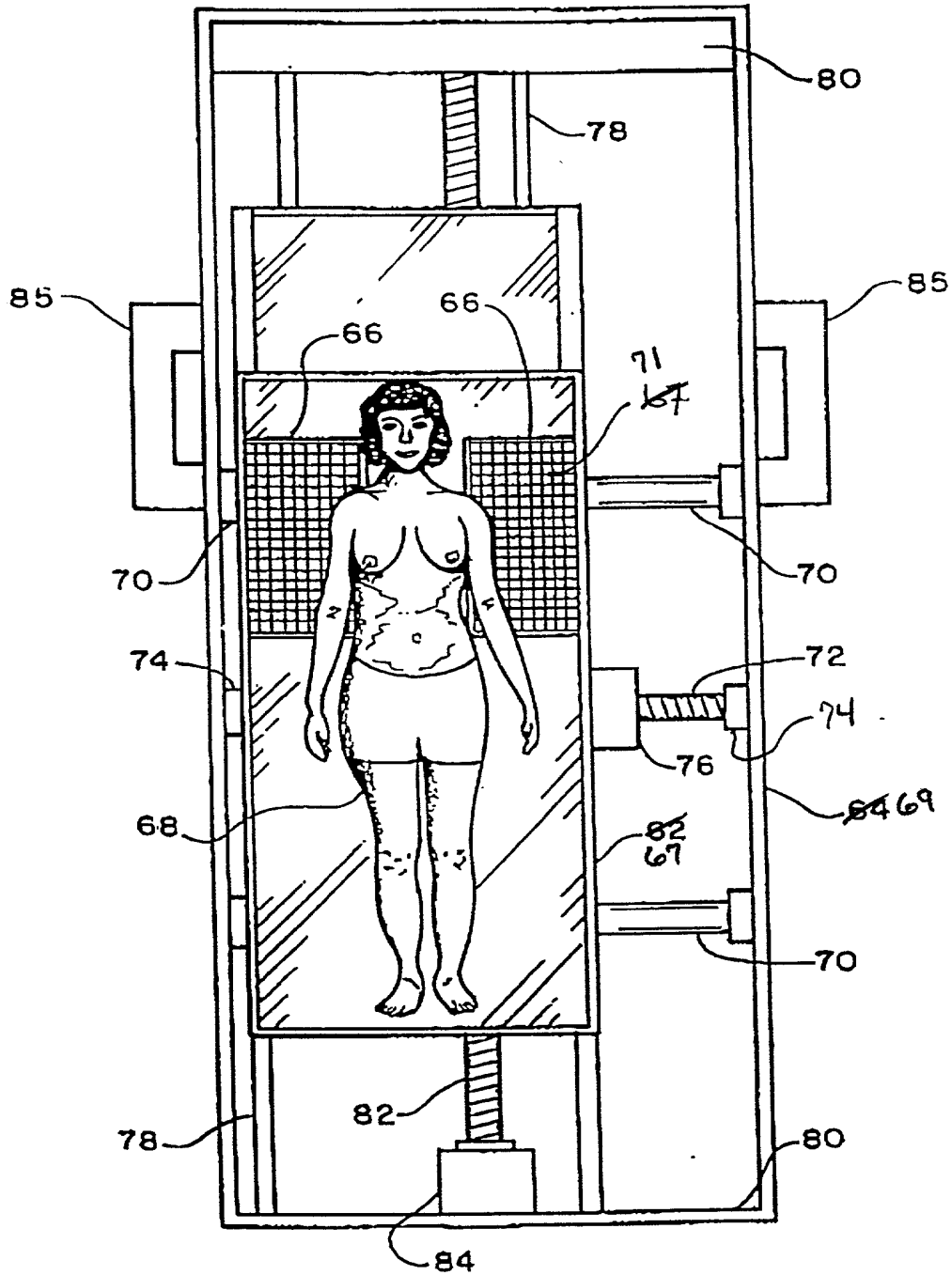
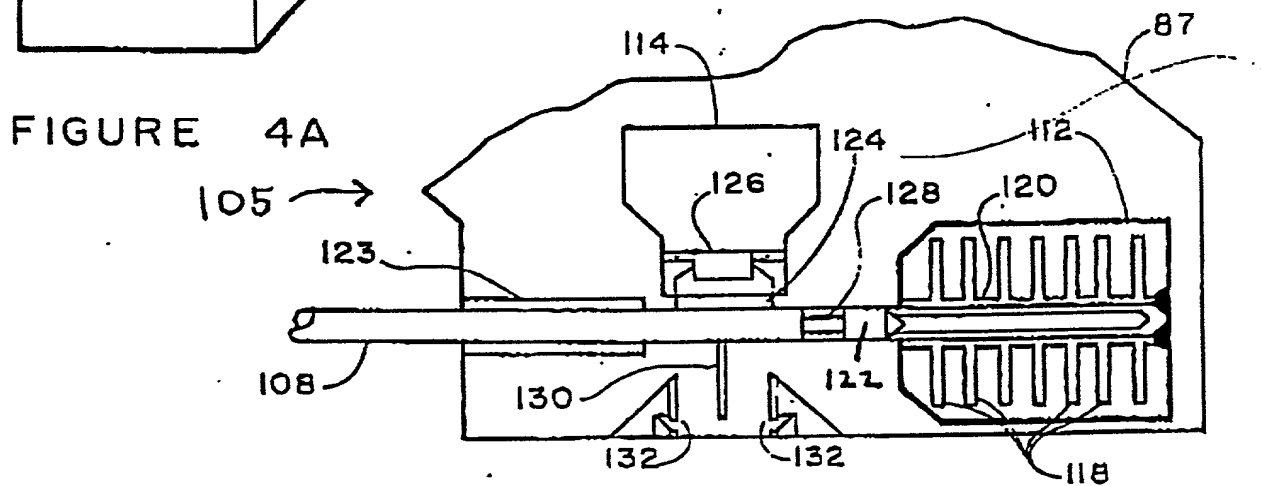
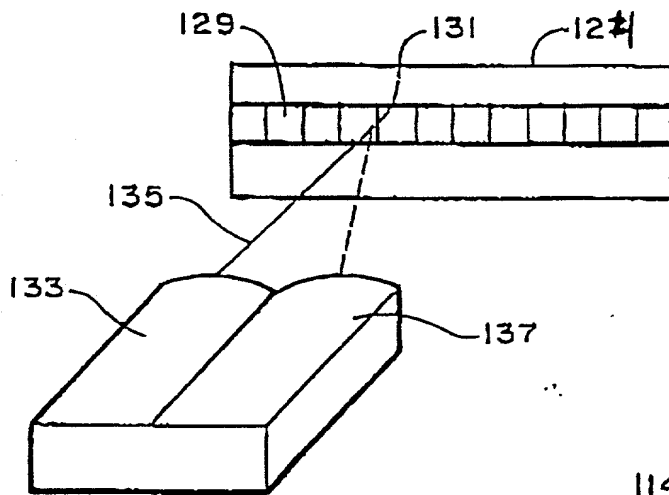
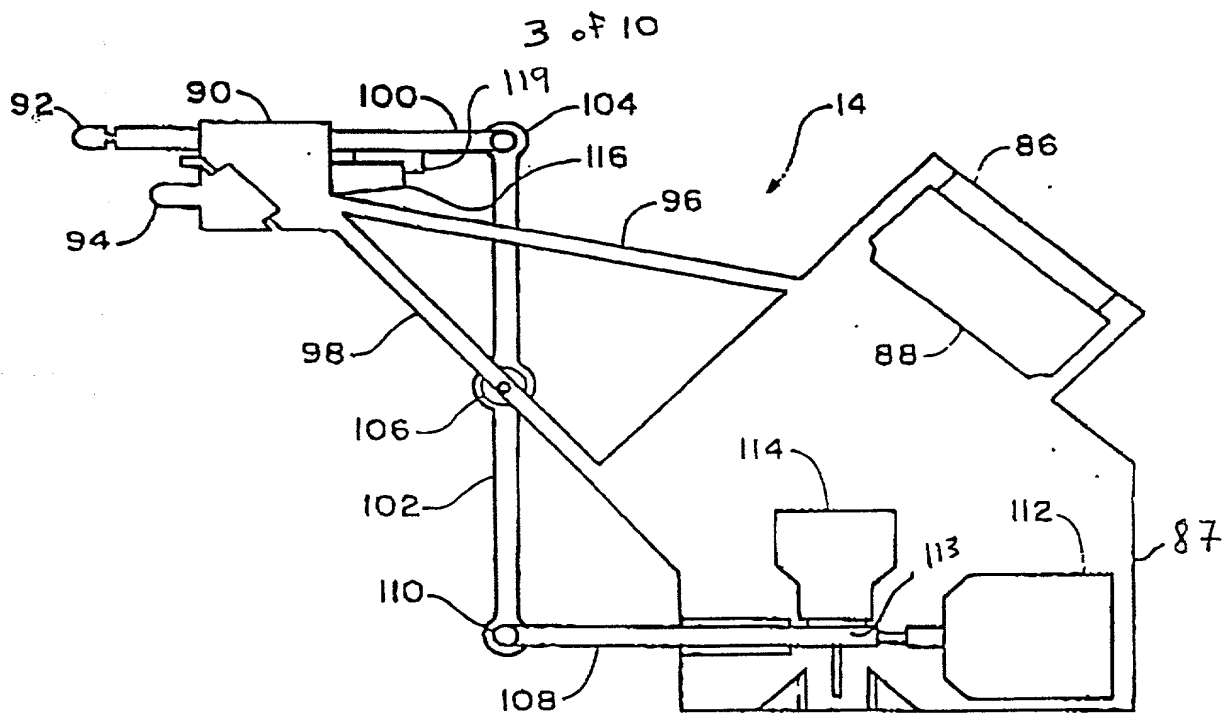


FIGURE 2

FIG. 3



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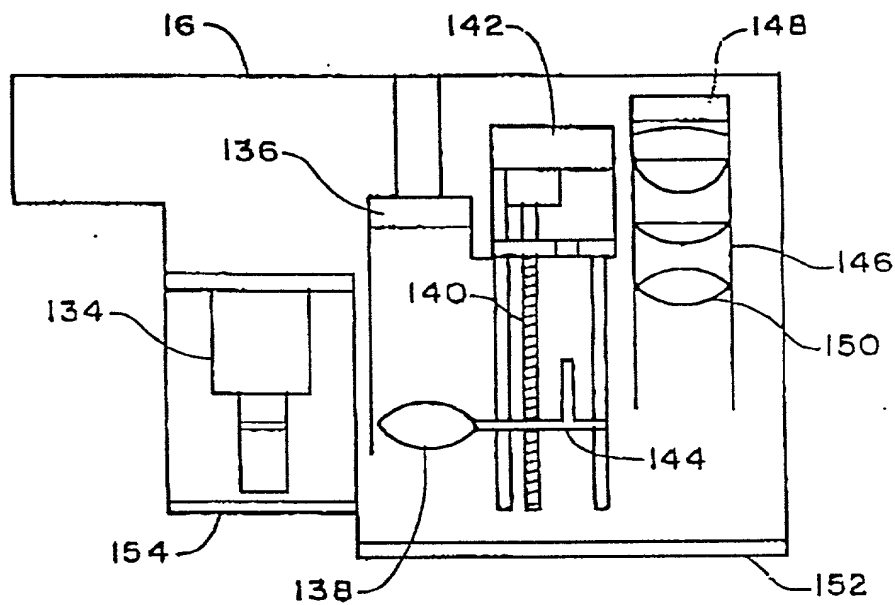


FIGURE 5

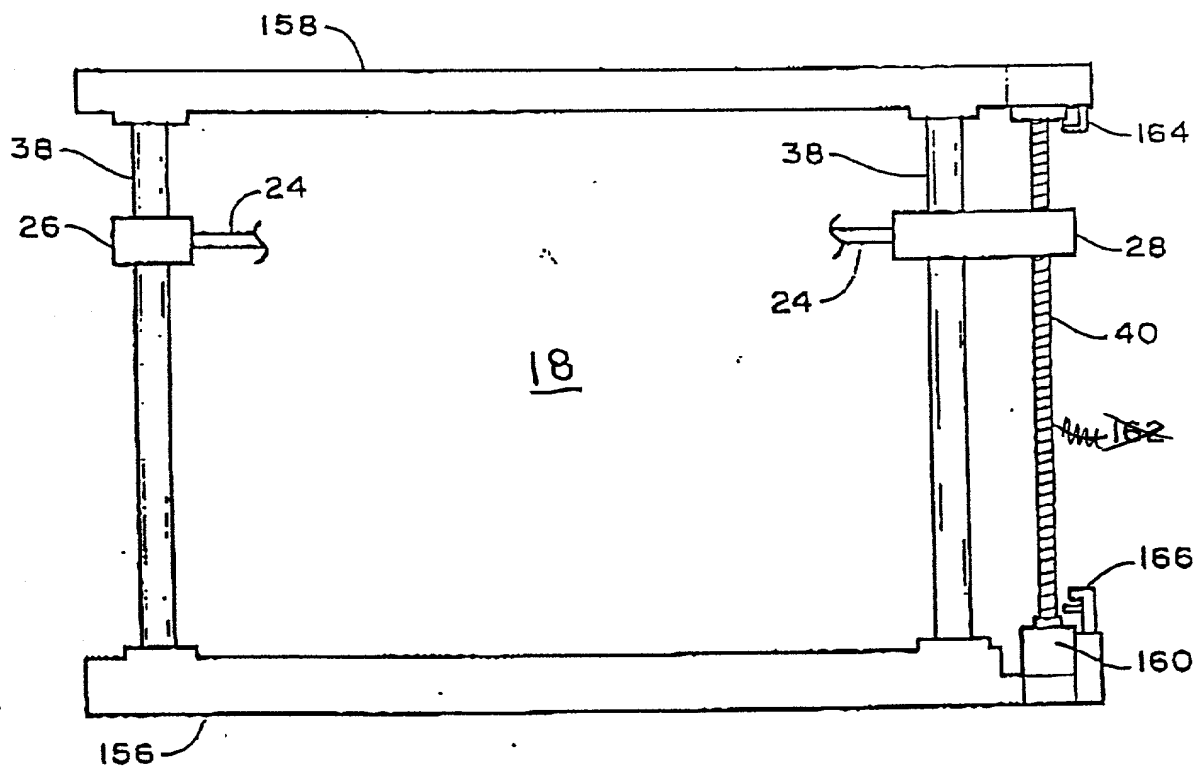
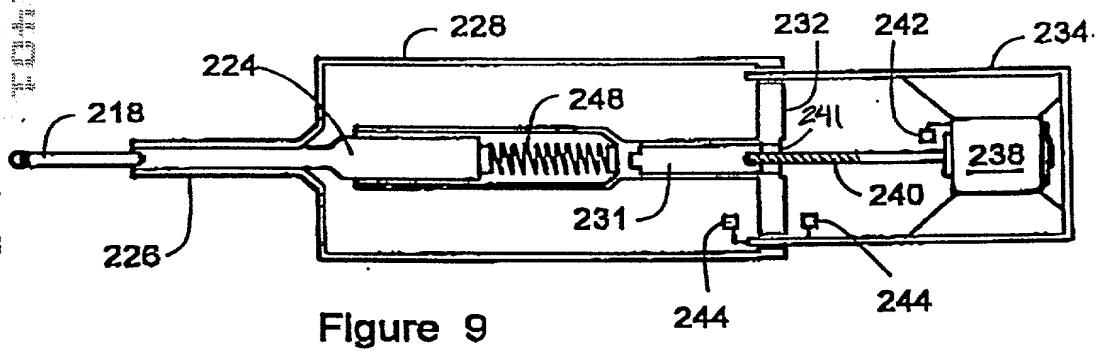
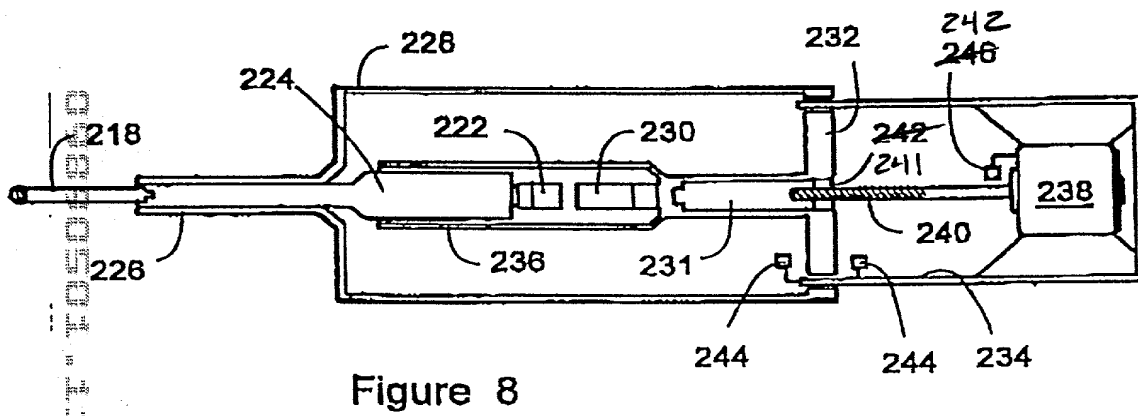
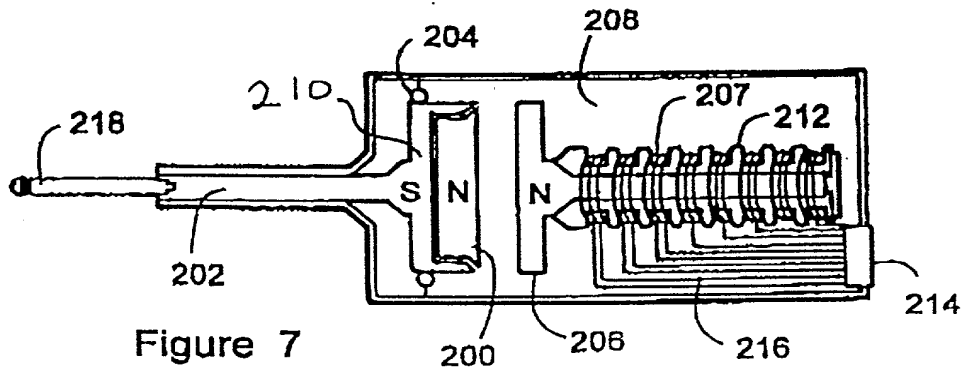


FIGURE 6

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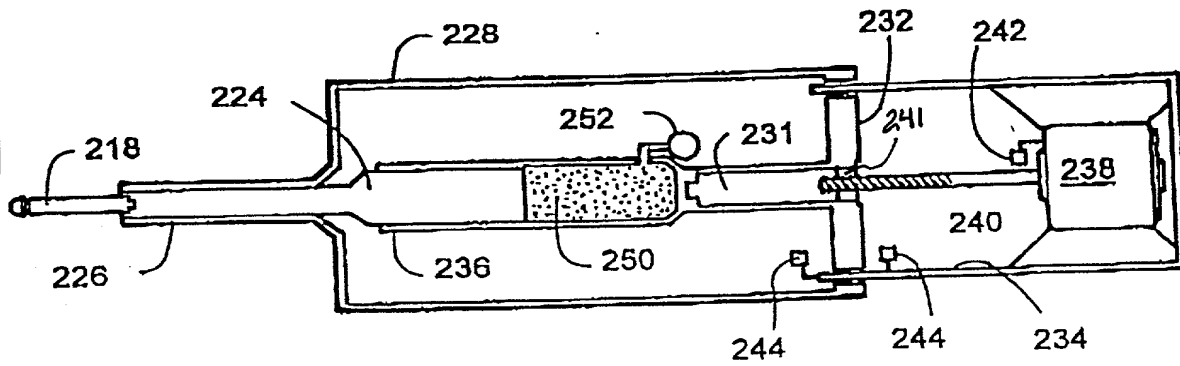


Figure 10

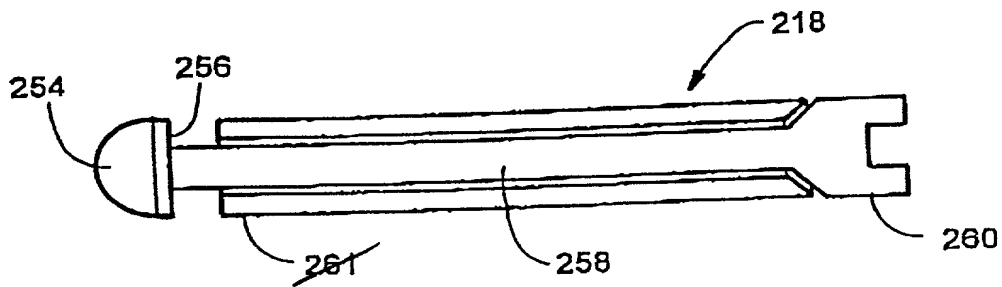


Figure 11

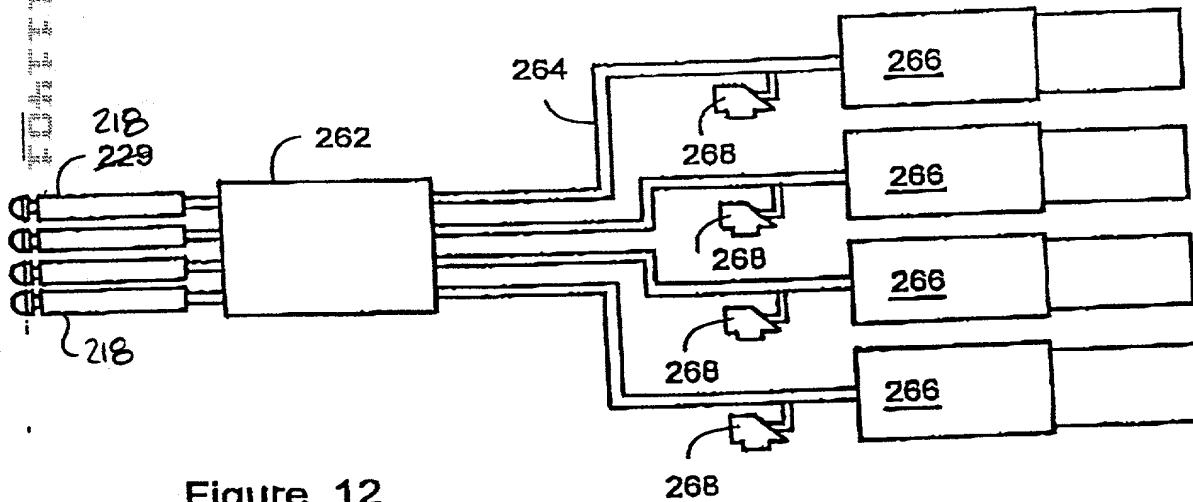
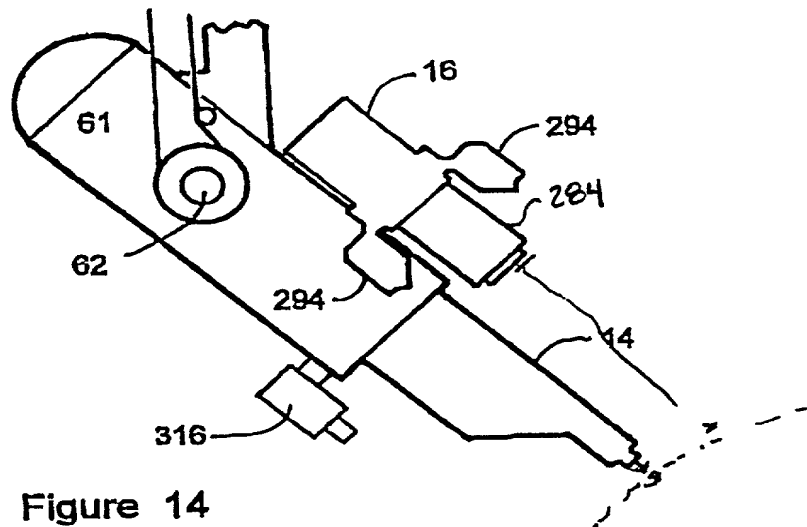
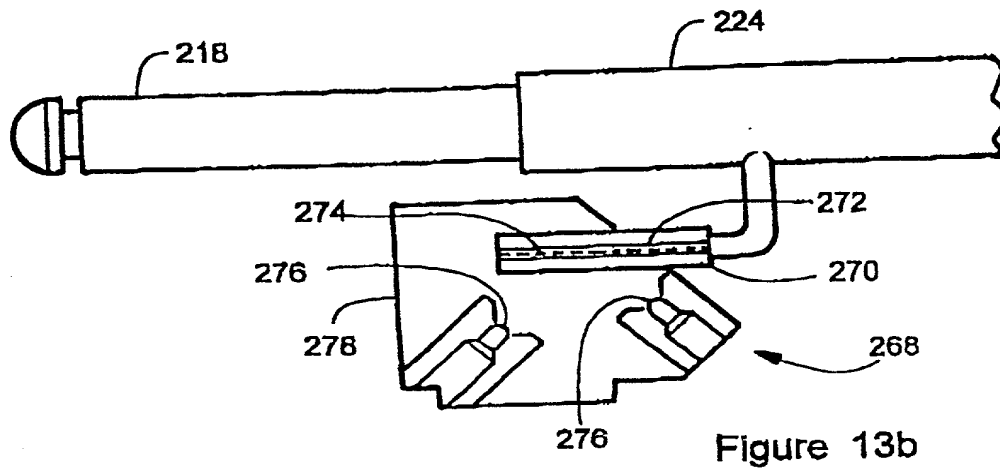
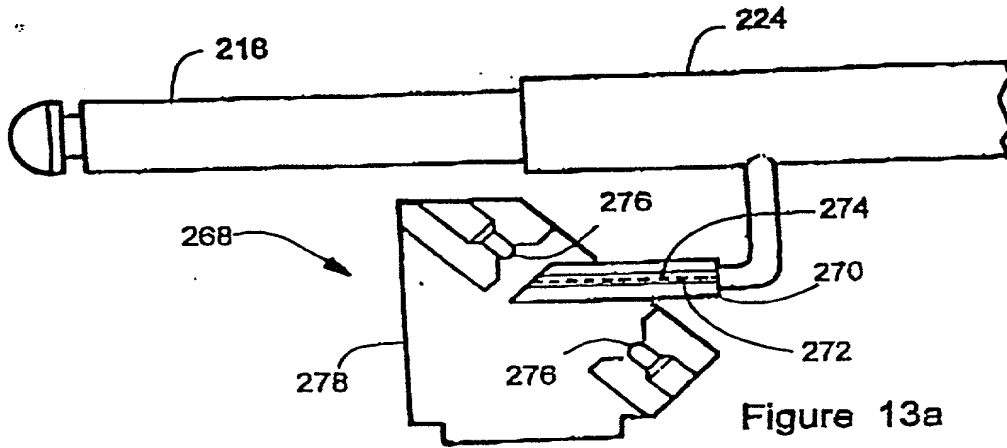


Figure 12



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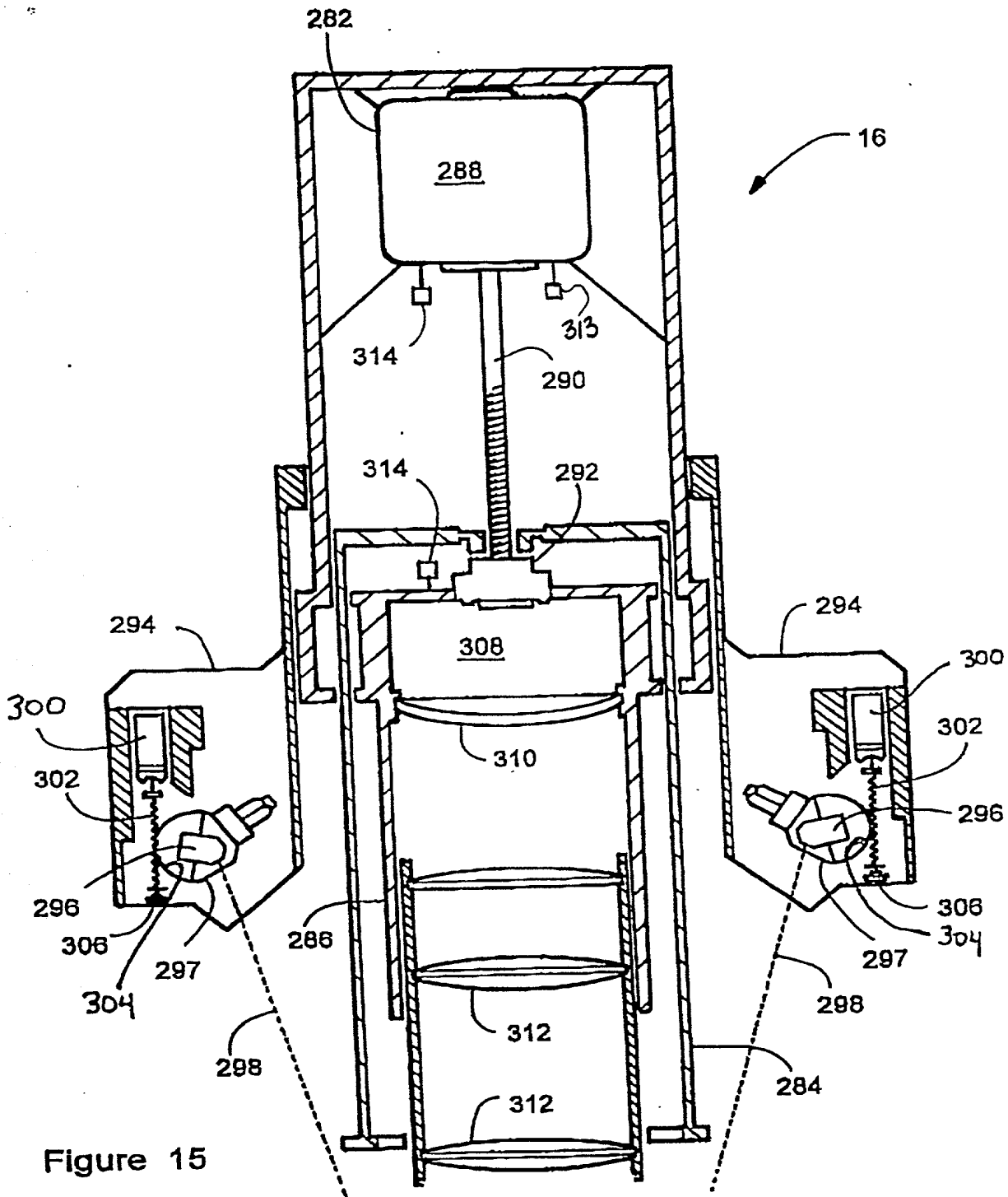


Figure 15

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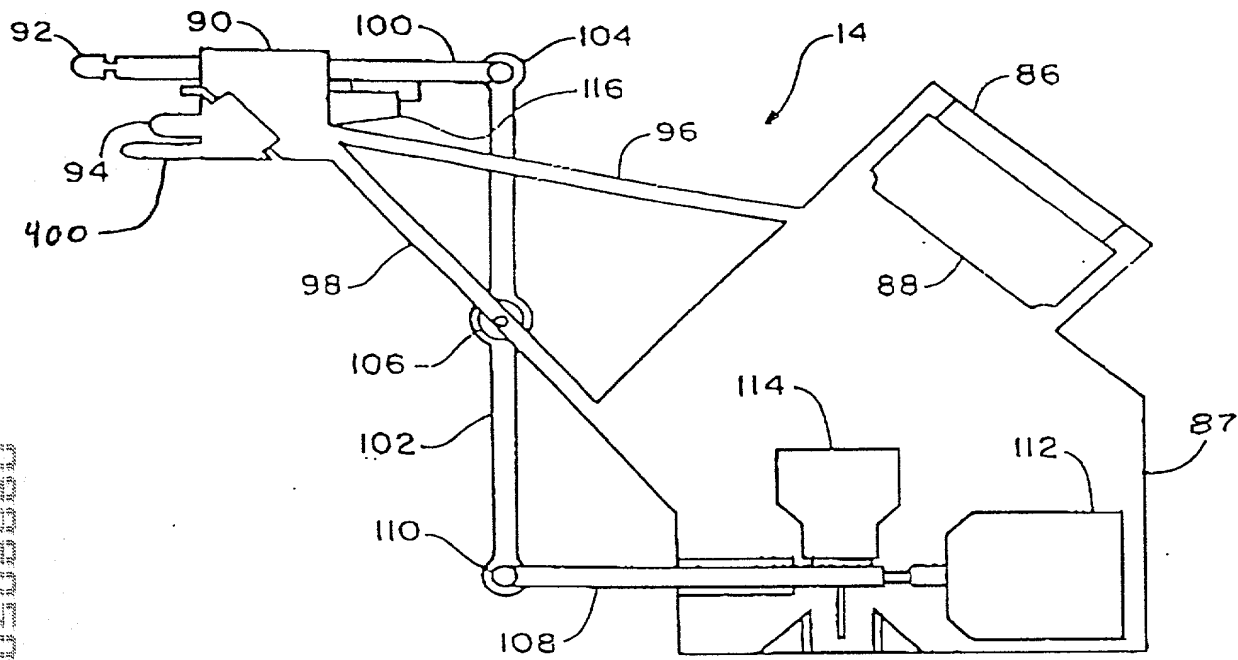


FIGURE 16

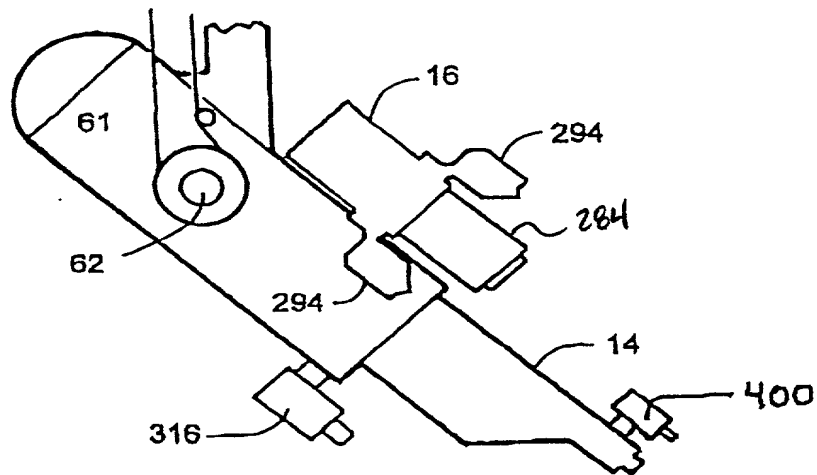


Figure 17

FIG 18 A

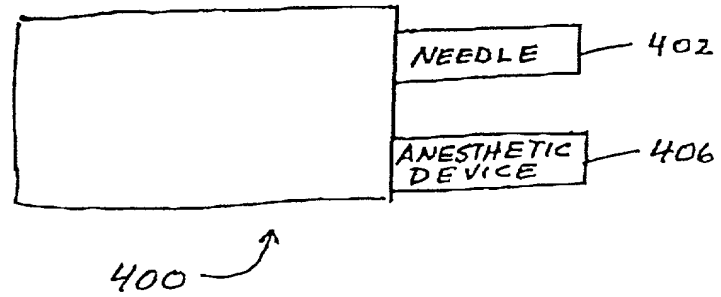


FIG 18 B

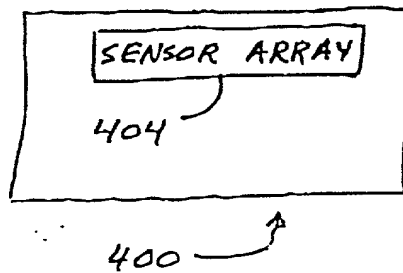
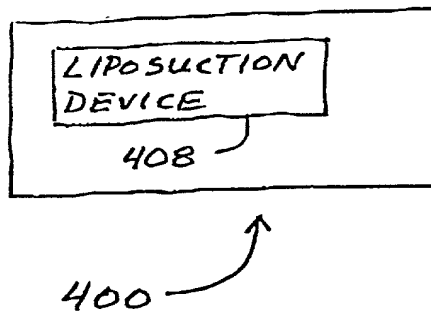


FIG 18 C



- 1 -

APPARATUS AND METHOD FOR DETECTING ANOMALIES IN HUMAN TISSUE

Invented By
Farid Soulier
Jeffery L. Garwin

REFERENCE TO RELATED APPLICATION

This application claims priority to U.S. Patent Application Ser. No. 09/241,193 entitled "Apparatus for Detecting Very Small Breast Anomalies" filed on February 1, 1999, which is incorporated herein in its entirety by reference.

FIELD OF THE INVENTION

This invention relates to apparatus and methods for detecting human tissues, and in particular for detecting very small anomalies such as tumors in human tissue such as a breast. The invention includes tissue mapping, the detection of tissue anomalies, generating an electrical signal and graphical data corresponding thereto, and automated tissue imaging and sampling for characterizing detected tissue anomalies.

BACKGROUND OF THE INVENTION

The early detection of anomalous human tissue, and in particular detection of undesirable tissue such as fat, fibrous tumors, or cancerous tissue is a much felt need. For example, recent findings indicate that one out of eight women will develop breast cancer, the second leading cause of death in women. The earliest indication of breast cancer generally is the occurrence of a painless lump, sometimes associated with nipple discharge and skin retraction. Unfortunately, later, more obvious and less survivable indications of cancer are generally due to metastases to bone, brain, lungs and liver. Accordingly, early detection of anomalous tissue and tissue changes is essential for improvement of survivability and effective treatment. Attempts at early detection through monthly self-examinations and mammography have proven beneficial but have

not satisfied the need for more effective methods of early detection and corresponding treatment.

By way of example, if small lumps, less than 20 mm, can be detected early they can then be diagnosed by a biopsy and treated should the lump be found to be malignant. Accordingly, early detection would allow for less invasive treatment such as a lumpectomy with possible radiation treatment of axillary nodes making less likely the need for a modified radical mastectomy with axillary node dissection. In addition through early treatment, the five-year survival rate maybe improved by as much as 85 percent. Absent early detection, distant metastasis are likely reducing survival rates to 10 percent or even less. The present invention address this very critical need.

Although early detection is essential, it can be difficult to achieve even by skilled physicians. Monthly self examinations have been shown to be helpful, particularly when followed by the examination of a physician in the event something is detected. It is, however, difficult and often unlikely for an unskilled person to do a thorough examination or detect very small lumps.

Presently, anomalies in tissue like the breast are detected mostly by periodic palpation by the hand of a physician or radiographic mammography. To be effective, however, hand palpation must be frequent, particularly in older women in order to detect tumors before they can metastasize. Unfortunately the subjective nature of hand palpation and the frequency required to make these examinations effective are often tremendous limitations that render palpation examinations ineffective due to convenience, availability, and cost. In addition, mammography is also troublesome due to the concern of accumulated radiation exposure from too frequent mammograms. It is also known that mammography, unlike palpation, can be limited as it may not detect very small tumors, particularly in the denser breast tissue of younger women.

In addition to anomalies, it is also very important that changes in tissue structures be detected and monitored over time. The problem, therefore, is how to detect minor changes in tissue. For example, hand palpation of issue may not reveal very small changes and anomalies within breast tissue until the tissue changes are so large or the anomalies so prominent that they can be detected and no longer responsive to early

treatment.

Another problem limiting the effectiveness of hand palpation is that it is not possible to record, retain and at a later time recall historical data of prior detected anomalies, including their location and the nature of the changes over time. This is particularly the case for soft anomalous tissue that is located further from the surface of the skin with diameters that are less than 10 mm. It is also known that anomalies deeper in the tissue of large breasts are particularly difficult to detect by hand palpation. Even if detected, it is often not possible to characterize the tissue or changes in the tissue due to the subjective nature and lack of standards for hand palpation which almost entirely depends on the skill and sensitivity of the examining physician.

Accordingly, the present invention address each of the aforementioned problems and urgent needs in the art for improved apparatus and methods for early detection of tissue anomalies and changes in tissue structures, particularly very small anomalies in breast tissue, as well as the urgent need to objectively determine tissue characteristics and produce, maintain, and compare tissue mapping and images of the tissue and its characteristics over time.

SUMMARY OF THE INVENTION

The present invention is an apparatus and method for detecting anomalies in human tissue. In one embodiment of the invention, the apparatus and method includes palpation by at least one palpation device for palpating tissue such as a human breast tissue and detection by at least one detector for detecting the time, distance traveled by, and the velocity of motion of the palpation probe. The apparatus and method includes measurement by a controller in communication with the palpation device and the detector for measuring a predetermined diagnostically relevant tissue characteristics from the probed breast tissue.

In one embodiment of the invention, the apparatus automatically scans, maps, and palpates an entire breast in a continuous manner, and compares adjacent tissue densities in order to detect changes in the physical characteristics of the breast tissue. Tissue density is measured across the entire breast and differentiated by means of relativistic or historic data in order to detect tissue changes and anomalies including their location and

size. Further, the invention records, retains and recalls historical data of the detected anomalies and detected tissue characteristics for comparison and mapping of the data, including anomaly location and changes over time. Although breast tissue is used as an example of the tissue under investigation throughout this disclosure, it is to be understood that any tissue structure can be palpated and characterized by this invention.

In another embodiment of the invention, the apparatus includes a platform on which a patient is positioned in a consistently similar manner each time the patient is tested. The platform is controlled by a location device such as an optical or video detector. A detection device such as a palpation probe is mounted on a carriage for movement in at least three directions adjacent to the patient. The location device continuously positions the patient so that the detection device can measure the tissue characteristics of the selected tissue under investigation.

The palpation device includes at least one probe or finger-like palpation end movable toward and away from the surface of the selected tissue in order to palpate the breast in the same general manner as a physician. The palpation device includes a probe that is maintained perpendicular to the selected tissue and movable across the entire surface of the selected tissue or beyond.

Information sensed by the palpation device is collected, stored and displayed in a manner that will show details of detected anomalies for comparison with historical data, and so that further testing, including automated biopsy and treatment, if required, can be performed. For example, a sampling device such as a biopsy needle or an aspiration device may be incorporated with the invention. Alternatively, the sampling device may also include devices such as an electromagnetic sensing device, temperature measuring device, or an ultrasound device. In addition, the invention may be used to treat a patient by directing radiologic, chemotherapeutic treatments, or even surgical instruments that are directed by, or attached to the movable arm provided by, the invention.

Although the invention may be used to characterize breast tissue, it is understood that the invention may be used to characterize any tissue such as, but not limited to, the face, abdomen, thighs, and buttocks, which may be measured by palpation to measure and locate tissue structure such as subcutaneous fat. Further, detected regions of fat can

be located and removed by the invention by a liposuction device that is directed by the invention. In addition, the invention may be used to palpate and detect lesions of the skin.

BRIEF DESCRIPTION OF THE DRAWINGS

5 For the purpose of illustrating the invention, there is shown in the drawings a form which is presently preferred; it being understood, however, that this invention is not limited to the precise arrangements and instrumentalities shown.

Figure 1 is an illustration of a detection device for detecting anomalies in human tissue according to the present invention.

10 Figure 2 is an illustration of a patient positioning platform for use with the detection device shown in Fig. 1.

Figure 3 is an illustration of a detection head and actuator according to the present invention.

15 Figure 4 and 4A illustrate a position and movement measurement device used with the detection head and actuator shown in Fig. 3.

Figure 5 is an illustration of a locator head assembly according to the present invention.

Figure 6 is an illustration of a vertical positioning mechanism for use with a detection device.

20 Figures 7-10 illustrate alternate embodiments of a detection head according to the present invention.

Figure 11 illustrates a palpation tip for a detection head according to the present invention.

25 Figure 12 illustrates a detection head having a plurality of parallel palpation tips according to the present invention.

Figures 13a-13b illustrate an actuator with an encoder according to the present invention.

Figure 14 illustrates an optical locating head and detection head mounted to a carriage according to the present invention.

30 Figure 15 illustrates the internal components of an alternate embodiment of a

locator head assembly according to the present invention.

Figure 16 illustrates a detection head and actuator having a sampling device according to the present invention.

Figure 17 illustrates an optical locating head and detection head having a sampling device mounted to a carriage according to the present invention.

Figures 18A-18C illustrate alternate embodiments of sampling devices according to the present invention.

DETAILED DESCRIPTION OF THE INVENTION

Referring now to the drawings, wherein like numerals indicate like elements, there is shown in FIG. 1 an illustration of one embodiment of an apparatus 10 for detecting anomalies in human tissue according to the present invention. In one aspect of the invention, the apparatus 10 includes a carriage (also referred to as a robot arm) 11 that is mounted at a proximal end to a horizontal support 12 for movement therealong, and a detector 14 (also referred to as a detection head) that is mounted at the distal end of the carriage 11. The detector is shown in more detail in FIG.s 3 and 4 and is used to detect the characteristics of tissue by palpation. A locator 16, for locating the position of a patient relative to some reference, is mounted to the ~~detector 14~~ ^{carriage 11} for movement therewith. Data is produced by the palpation device and collected, stored and displayed in a manner that will capture details of the detected anomalies for comparison with historical data. The invention provides data about the tissue under investigation by means of an automated biopsy and treatment by means of surgical attachments for the delivery of radiologic, chemotherapeutic, or laproscopic surgery.

For example, the digital information can be received, stored, processed or displayed in a similar manner to existing medical devices such as a CAT scan or MRI. In addition, the invention can produce multi-dimensional images that may be viewed on conventional computer monitors. Images may be produced using color to indicate areas of differing tissue density. These images may be further enhanced by combining tissue density information with tissue color and temperature information to detect and track even smaller tumors in discrete tissue areas.

Horizontal Movement

In ^{one} ~~another~~ embodiment of the invention, ^{the support structure of which} ~~which~~ is shown in detail in FIG. 6, the detector 14 is positioned over the patient and provided with horizontal movement by means of a horizontal support 12 that is mounted on a vertical support mechanism 18, allowing the horizontal support 12 to move in a vertical direction. The horizontal support
5 12 includes a traveler 20 that rides on bearings 22 along rods or tubes 24 that are secured at their ends to end blocks 26,28. A lead screw 30 is driven by a drive motor 34 and extends between a pair of end blocks 26,28 and bearings 32. Lead screw 30 extends through correspondingly threaded openings 36 of the traveler 20 so that the traveler 20 will move to the right or left as the lead screw ³⁰ is rotated in one direction or the other, and limit switches 37 are used to prevent over travel of the traveler 20. Guide rods 38 extend
10 vertically through the end blocks 26,28 so that the horizontal support 12 can be moved vertically by means of a lead screw 40 that extends vertically through one end block 28.

The carriage 11 includes a base 42 secured to the traveler 20. A motor 44 within the base 42 rotates a screw 46 that is threaded into an intermediate body 48 to raise and lower ^{the intermediate} ~~that~~ body, as the screw 46 is rotated one way or the other. A pair of guide rods 50 extend through a bracket 52 to guide movement of the intermediate body 48. A lower body 54 is secured to the intermediate body 48 for rotation relative thereto. A motor 56 is mounted on the intermediate body 48 with the lower body 54 mounted on the motor shaft ⁵⁸ ~~56~~ for rotation with the shaft ⁵⁸ ~~56~~.
15

20 Vertical Movement

The detector 14 is positioned over the patient and provided with vertical movement by means of a mechanism for raising and lowering the entire carriage 11, ~~is as~~ shown in FIG. 6. The carriage 11 is supported by a pair of vertical guide rods 38 that extend from a sturdy base 156 to a top plate 158. A pair of end blocks 26,28 support the
25 horizontal support 12 and provide vertical movement therealong.

A motor 160 rotates a sturdy lead screw ⁴⁰ ~~162~~ threaded through a block 28. An upper limit switch 164 and a lower limit switch 166 prevent movement of the horizontal support 12 beyond desired limits. For a very strong, sturdy assembly, the base 156 will rest on the floor or a sub-floor so that the platform ⁶⁷ ~~assembly 64~~ could be positioned

within the frame formed by the base 156, the top ^{plate}~~support~~ 158 and the guide rods 38.

Positioning Arm

An arm 61 is pivotally mounted at a pivot 62 on a bracket 64 that is mounted on the distal end of the lower body 54. A motor 60 on the lower body 54 drives a pulley ~~62~~⁶³ on the arm 61 through a jackshaft ⁶⁵~~64~~. Thus, the entire carriage 11 can be moved horizontally by the horizontal the support 12, and vertically by the vertical support 18. The lower body 54 of the carriage 11 can be rotated 360°. The arm 61 carries the detector 14 which can be pivoted through at least 120°. The arm 61 can also carry and operate other devices such as, but not limited to, attachments for the delivery of acoustic, radiologic, chemotherapeutic treatments or laparoscopic surgery. The combination of movements just described, permit the detector 14 to be positioned in any desired position relative to any portion the surface of human body, particularly a breast.

Although a particular positioning arrangement of the detector 14 has been described, it is understood that the invention can include any type of positioning system that will provided several degrees of freedom of movement for the detector 14 or other devices.

Position and Location System

In one embodiment of the invention, an investigation of a selected body part or region is started by positioning the patient on a platform (also referred to as a bed) ⁶⁷~~62~~ that is affixed to a position adjusting assembly ⁶⁹~~64~~ such as that shown in FIG. 2. The platform ⁶⁷~~62~~ is typically positioned below the detector 14 of FIG. 1. The platform ⁶⁷~~62~~ has a comfortably padded upper surface and a matrix board 66 with a location pattern ⁶⁷~~67~~, that is typically positioned adjacent to the shoulders of the patient ⁷¹~~68~~.

The matrix board 66 and pattern ⁷¹~~67~~ are used to maintain registration between the specific points of the patient's body under investigation and the acquired measured data. In addition, the matrix board 66 and pattern ⁷¹~~67~~ are used to maintain registration between subsequent measurements taken at different times for the same patient 68.

For example, optical measuring means such as, but not limited to, a video camera, a fiducial reference target, or a laser location device can be used to locate the exact position of the patient or selected body parts such as arms, shoulders and neck

relative to the matrix board 66 and its pattern ⁷¹67 during an investigation.

In subsequent investigations, the patient 68 is positioned on the platform ⁶⁹62 at a later time, and the optical system, and with or without the aid of adaptive software techniques, the invention will correlate prior and presently collected location data measurement data with multiple prior measurements. Further, movement by the patient 68 that may introduce errors in the measured data can be corrected during the investigation by error correction techniques provided by the optical system. Although it is desirable ~~for~~ ^{that} for the patient 68 be placed in the same position for each investigation, it is not required since that the invention can correct for any change in position by means of position reference data collected during each periodic investigation.

Referring to FIG. 2, the underside of platform ⁶⁷62 includes conventional tubular bearings through which a pair of horizontal guide rods 70 pass. A central threaded rod 72, driven by a motor 76, engages end bearings 74. As the motor ⁷⁶72 rotates the platform ⁶⁷62 is moved right to left. The platform ⁶⁷62 is similarly moved up and down by means of a pair of guide rods 78 secured to end walls 80 of assembly ⁶⁹64 and driven by a motor 84 that rotates a threaded rod 82 which moves the platform ⁶⁷62 as desired.

The invention provides a means to control the position of the patient for consistent reinvestigation. This is accomplished by means of the platform ⁶⁷62 and a location device (also referred to as a sensor or a head) 16 which is shown in FIG. 5. The location device 16 provides accurate location information for positioning the patient 68 on the platform ⁶⁷62 or for correlating the data with subsequent or prior measurements by means of geometric translation which can be achieved by pattern recognition or reference to a fixed fiducial reference.

For example, a digital camera 134 may be used to produce a digitized image of the tissue under investigation. The image may then be compared by a computer system or technician to prior or subsequent images. A white light source 136 may also be used to produce a three dimensional image. As shown in FIG. 5, the light source 136 is employed with an auto-focus system having a lens 138, and a lead screw 140 rotatable by a motor 142 and threaded through a lens mount bracket 144 for focusing a light spot on the surface of the tissue under investigation. The spot of light is moved transversely

and focused at different depths along the tissue surface. Data of the focus position of the lens 138 is collected and used to produce a three dimensional image of the tissue surface.

In another aspect of the invention as shown in FIG. 5, a laser scanner 146 may be used to create a three-dimensional image. The laser scanner 146 includes a laser emitter 148 and a focusing system 150 for producing a focused laser spot on the surface of the tissue under investigation. For example, a laser operable in the range of 680-820 nm with a power level about 0.0095 should provide sufficient laser power to produce an image without damaging the tissue under investigation.

In all aspects of the invention, prior and subsequently collected image data can be used to translate position data of the tissue under investigation. This feature provides enhanced capabilities in the examination of anomalies in the tissue under investigation. For example, a three-dimensional image can be divided into a matrix of cubes or slices with geometric indicia (e.g., a cube might be identified as cube 2,4,9 on an x-y-z axis basis) and locations can be directly compared between the light spot image and the probe palpation locations.

Palpation Systems

One embodiment of the detector 14 according to the present invention is shown in FIG. 3. The detector 14 is shown with a removable connection 86 for attachment onto a rotatable arm 61. The detector 14 has a palpation probe housing 90 for supporting a palpation probe or finger 92 and a sensor 94. The sensor 94 includes, but is not limited to, a device for sensing distance, acoustic waves, x-rays, MRI, color, and temperature. The sensor 94 may also be mounted to the detector's main housing 87. The palpation probe 92 is designed to simulate a physician's finger during a palpation investigation like that in a manual breast examination. In a preferred embodiment, the palpation probe 92 is composed of a disposable material, such as, but not limited to, glass or plastic.

Distance is measured by means of a sensor 94, which is an autofocus system like that used in cameras. The auto-focus system can provide precise data such as the distance between the breast surface and a known reference point within the sensor. In another aspect of the invention, a plurality of spaced range finders can be used to measure the angle with respect to the breast surface so that the orientation of the palpation probe

92 is maintained at a pre-determined angle such as, but not limited to a, perpendicular to the tissue under investigation.

Color is sensed by a color sensing device such as a photo-detection diode or spectrum detection sensor. In addition, a prism or diffraction grating for dispersing incoming light and refracting each color of light to an independent photoelectric sensor may also be used.

Referring to FIG. 3, one aspect of the invention the palpation probe 92 is secured to the distal end of a first shaft 100 which is slidably connected to the housing 90 and pivoted, at its proximal end, to the distal end of a first arm 102 at a pivot point 104. The first arm 102 is rotatable about an axis 106 that is centrally located along a second arm 98. The proximal end of the first arm 102 is pivotally connected to a drive shaft 108 at a second pivot point 110. When the drive shaft 108 is moved axially by an actuator located within an actuator housing 112, which is shown in detail in FIG. 4, the first shaft 100 and the palpation probe 92 move a proportional distance in the opposite direction.

The motion of the palpation probe 92 is then measured to determine time, distance traveled, velocity, and resistance encountered by the probe 92 as it comes in contact with the tissue under investigation. For example, an optical reading device 126 having a laser source is located in a reader housing 114 for detecting movement of the palpation probe 92 by means of an optical encoded gradient 113 attached to the drive shaft 108. The parameters of time, distance traveled, and rate thereof, are used to determine a characteristic value of the tissue under investigation in response to the feedback resistance experienced by the palpation probe 92 when it is pressed against the tissue under investigation.

To further improve the accuracy of the measurements, a position error correction sensor 116 is used in cooperation with a position detection member 119 such as, but not limited to, an optical gradient, inertial displacement device or motion sensor, that is attached to the first shaft 100 to detect and correct positioning errors. The position error correction sensor 116 is used to correct movement and position errors of the components of the detector 14. Movement of the palpation probe is accomplished by the activation of ~~a first coil~~ ^{magnetic coils} 118, ^{are} which is shown in detail in FIG. 4. Slight changes in position of the

tissue under investigation, like that caused by breathing, can be sensed by the palpation probe and a corresponding position correction signal ^{can be} ~~that is~~ sent to selected coils of the ~~first coil~~ 118 to correct displacement errors.

magnetic coils

In one embodiment of the invention, the palpation probe 92 is moved by a series of electromagnetic coils 118 that are arranged in a ~~uniformly~~ spaced relationship along a central tube 120. In a preferred configuration, the electromagnetic coils 118 may be formed as a continuous helix to ~~form~~ ^{form} a solenoid. An end shaft 122 is axially secured to the proximal end of the drive shaft 108 and extends into a tube 120.

An end shaft 122 is formed from a magnetic material so that when the coils 118 are actuated sequentially, beginning with the coil adjacent to the end shaft 122, the magnetic forces in the coils 118 will pull the end shaft 122 into the tube 120. Alternately, the coils 118 are actuated individually in a sequence or by applying incrementally increasing voltages to the coils 118. The extension of the drive shaft 108 is controlled by the movement of the end shaft 122 which can be adjusted by a threaded mechanism 128. The maximum excursion of the drive shaft 108 is limited by a pin 130 extending from the drive shaft 108 and a pair of limit switches 132.

The magnetic force applied is sufficient to advance the palpation probe 92 to compress the tissue under investigation but not enough to cause discomfort or damage to the tissue. The time and distance the probe advances will be in proportion to the density of the tissue, resulting in less time and movement for dense tissue and more time and movement for less dense tissue.

In operation, ^a ~~the~~ first coil 118 is actuated to move the palpation probe 92 a predetermined force, distance, time, or some combination thereof. The first coil 118 is energized in a step-wise fashion at about 250mv increments from 0 to 10 volts, and the change in force is about 10 grams per mm² per step. When the probe fails to move a predetermined distance for a predetermined time, additional force is applied by means of ^a ~~the~~ second coil 118. It is to be understood that additional coils similarly operated, can be added as required.

The resistance characteristic of the tissue under investigation is determined ~~as~~ when the applied pressure, distance traveled or time of pressure reaches a predetermined

value. The parameters of force, distance or time are measured at the predetermined value and the parameter information is then transferred to information storage means and/or to a controller for processing, analysis, and the production of multi-dimensional images.

In one aspect of the invention, the palpation information including, but not limited to, distance, force, time, resistance, and characteristic value of the tissue under investigation, are obtained by encoding and transmitting the acquired palpation information. As shown in FIG. 4, a laser optic card 124 associated with the shaft 108 is read by a laser card reader 126 which transmits the encoded information to a storage device or the controller 17 for processing. The controller then processes the information as required for use by other devices or in a manner similar to ~~X~~CAT systems or equivalent devices.

An example of a laser card 124 that is to be used with the laser card reader 126 is shown in FIG. 4a. The card ~~127~~¹²⁴ has a series of reflecting areas 129 that are separated by non-reflective areas 131. The non-reflecting areas 131 of the card ~~127~~¹²⁴ can be light absorbing or transparent. A laser transmitter 133 directs a laser beam 135 against the patterned area of the laser card 124. When the laser beam 135 hits a reflecting area, reflected light is picked up by a receiver 137. As the card 124 is moved in a direction transverse to the reader 126, the pattern of reflected pulses are counted to measure movement of the drive shaft 108 and the palpation probe 92. The reflecting areas can be as small as about 0.001 mm for more precise measurements of the motion of the palpation probe 92. Although only laser illumination has been discussed, it is to be understood that any form of illumination can be applied including, but not limited to, visible, infrared, or ultraviolet light, which may, or may not, be coherent, focused, columnated or diffused.

Palpation Actuators and Probes

In another aspect of the invention, a palpation detector for detecting changes in density of tissue is shown in FIG. 7. A permanent magnet 200 is mounted on a non-magnetic rod 202 that is movable along the axis of the rod centerline. Suitable guides 204 such as rollers, ball bearings, a sleeve or the like are provided for smooth, low resistance, axial movement of the rod 202. The permanent magnet 200 is proximate to

an electromagnetic coil head 206 mounted on a shaft 207 and fixed to a housing 208. The permanent magnet 200 and the electromagnet head 206 have common poles while the rod 202 has an opposing pole 210. Electromagnet head 206 is powered by any suitable number of powered coils 212 that are connected at a terminal 214 to a power source by supply wires 216. The magnets ^{200, 206} having common poles ~~they~~ ^{200, 206} will oppose each other pushing the magnets apart when the electromagnet coils 212 are activated. The intensity of the opposing force is adjusted by the number of coils 212 and the level of power applied thereto.

A palpation probe tip 218 is shown in FIG. 11, according to the present invention. The palpation probe tip 218 is mounted on the distal end of the rod 202 which is brought into contact with (or to a predetermined distance from) the tissue under investigation, such as a breast surface by the ~~positioning~~ ^{carriage} arm 11. The coil 212 is energized to increase the field around a shaft 207 to increase the field at the electromagnetic head 206 in order to force the permanent magnet 200 further away from the electromagnetic head 206, which moves the palpation probe tip 218 against the tissue. The tissue is depressed at the point of contact which transfers the tissue's elasticity characteristic in the form of a back pressure through the probe tip 218 and rod 202 ~~and onto~~ ^{head} the coil 206. ^{toward}

The amount of back pressure applied including variations thereof are measured by recording instrumentation associated with the processor 17. It is to be understood that this pressure measurement system can be incorporated with any palpation device disclosed herein. Additional embodiments of palpation detection and actuator devices are shown in FIG.s 8 - 14.

The detection and actuator device shown in FIG. 8 includes a permanent magnet 222 that is mounted at one end to an actuator rod 224 which is supported by a slidable sleeve 226 that is mounted on a housing 228. A tip 218 of the sort shown in FIG. 11 is secured to the other end of rod 224. A second permanent magnet 230 is mounted on a holder 231 that is coaxial with the rod 224. The permanent magnets 222, 230 are selected with common poles (north to north or south to south.) The holder 231 is supported on a disk 232 that is slidable within the housing 234 and coaxial with the rod 224. A sleeve 236 is preferably mounted on the holder 231 to aid in guiding the movement of the rod

224.

FIG. 11 shows a preferred embodiment of a palpation tip configuration 218. The tip configuration 218 includes a rounded endpiece 254 for contact with the tissue under investigation. Any suitable material may be used that can be inexpensively cleaned and made safely disposable is preferred. An end isolator 256, made up of an electrically insulating material is used to prevent static electricity discharge of the tissue. A core member 258 connects the endpiece 254 to a base 260 which is secured in any suitable manner, such as threads, to the rod 224.

In operation, the detector 14 is moved as discussed above to bring the palpation tip 218 into proximity with a selected location along the tissue under investigation. When the palpation tip 218 is initially brought into proximity to the breast surface, gravity causes the rod 224 and the permanent magnets 222 to move apart. A motor 238 mounted in a housing 234 drives a lead screw 240 which is threaded through a corresponding female thread ²⁴¹242 in a disk 232. The motor 238 may be any suitable motor, such as a low rpm DC motor or a stepper motor. Rotation of the lead screw 240 will move magnet 230 towards magnet 222 decreasing the intermagnet gap until the tissue resistance returns the intermagnet gap to a predetermined distance. The displacement of the holder 231 and the disk 232 is related to the tissue density characteristics of the tissue at the contact point. A sensor ²⁴²247 counts the revolutions of the motor 238 to measure the corresponding degree of movement of the palpation tip 218 into the tissue.

Conventional safety sensors 244 may be provided to limit maximum movement of disk 232 (and movement of tip 218 in accordance with disk position) to prevent damage to the breast. As mentioned above, the magnetic field between the magnets 222, 230 will act as a resilient mount for the palpation probe tip 218, limiting any damage or injury should the tip strike a breast or other surface.

FIG. 9 shows another embodiment of a detector 14 having a pair of housings 228, 234, an actuator rod 224, sleeves 226, 236, a palpation tip 218, a holder 231, a disk 232, a motor 238, and sensors 242, 244. Instead of spaced permanent magnets 222, ²³⁰236 a spring 248 is fastened between the proximal end of the rod 224 and the holder 231. The

spring 248 is selected to provide a bias to the two juxtaposed ends of the rod 224 and the holder 231 to a particular, predetermined spacing. When the detector 14 is positioned over the tissue the palpation tip 218 extends downwardly under the force of gravity. The motor 238 rotates to move the disk 232 and holder 231 toward the rod 224 until the gap
5 between the distal end of the holder 231 and the proximal end of the rod 224 is at the original predetermined distance. The total movement of the holder 231 is indicated by the number of revolutions of the lead screw 240 as measured by the counting sensor 242, which is indicative of the desired tissue characteristic.

Another aspect of a detector 14 is shown in FIG. 10 having a gas 250 interface
10 that is enclosed within a sleeve 236 at the proximal end of a rod 224. The sleeve 236 fits over the rod 224 in a sealing arrangement to prevent the pressurized gas 250 from escaping. Any suitable conventional seals may be used between the rod 224 and the sleeve 236.

The axial force applied to the rod 224 will change the gas pressure within the sleeve 236 which will be measured by a pressure sensor. When placed in contact with
15 the tissue under investigation, the contact pressure is sensed by the amount of pressure applied to the gas by the palpation probe 218. Pressure in the sleeve is adjusted by the rotation of the motor 238 which is counted by sensor 242. The amount of pressure applied by the rotation of the motor 238 is proportional to the desired tissue characteristic
20 such as hardness and density.

FIG. 12 shows another detector ¹⁴~~11~~ having a plurality of palpation probe tips 218 that are arranged in a parallel array and mounted on a corresponding number of actuator rods 262 for axial movement. In one aspect of the detector ¹⁴~~11~~, a plurality of offset extension connectors 264 made of inflexible cables are used to transmit motion by means
25 of transducers 266 that are connected to the output ends of the rods 262. An optical encoder and reader system 268 is incorporated to measure the movement of each palpation tip 218 during palpation of the tissue under investigation.

FIG.s 13a and 13b show two embodiments of the encoder and reader system 268 having a plurality of detectors 276 and encoder cards ^(strips)272. The encoder system 268
30 includes an encoder slide 270 that is secured to ^{the}~~a~~ rod 224. The encoder slide 270 is

secured to any suitable part of the rod 224 or to ^{the} a palpation tip 218, as desired. The encoder slide 270 is transparent and includes a strip 272 with reflective dots 274 (or, in the alternative transparent dots in an otherwise opaque strip 272).

Decoder sensors 276 mounted on a housing 278 are provided on opposite sides of the encoder slide 270 and secured to ^{the} a housing ²⁷⁸ 228 by any suitable mounting means. The decoder sensors 276 are optical or laser sensors having light emitters of the sort used to read compact disks. The dots 274 are reflective particularly against a transparent background which causes light to pass between the pair of light transmitting decoder sensors 276. As the encoder slide 270 is moved, light from the emitters is either reflected by the reflective dots 274 or transmitted through the disk and onto the ^{opposite} sensor 276.

Accordingly, the detected light indicates movement of the slide and the number of pulses of light received which are used to measure the distance of movement of the rod ²²⁴ 228 and the palpation tip ²¹⁸ 229. Alternatively, when the dots 274 are transparent against an opaque background, light pulses received at the detector decoder sensor 276 will indicate the distance of movement of the rod ²²⁴ 228 and the palpation tip ²¹⁸ 229. FIG. 14 shows another embodiment of the detector 14 in which the optical locating head 16 and detector 14 are both mounted at the end of the arm ⁷⁶¹ on carriage 11.

FIG. 15 shows and optical locator 16 having a motor housing 282 in combination with a detector 16. A lens enclosure 284 is secured to the motor housing 282 after precise positioning during manufacture of the assembly. A lens assembly 286 is slidably mounted within lens enclosure 284 for axial movement relative thereto. A motor 288 is mounted within motor housing ²⁸² and drives a lead screw 290 which is threaded through a nut 292 secured to lens assembly ²⁸⁶ 286 to move the lens assembly axially within lens enclosure 284.

Two laser beam positioning enclosures 294 are mounted on opposite sides of motor housing 282. Each enclosure 294 contains a pre-focused conventional (typically 680 to 850 nanometer) laser diode and light sensor 296. A prism 297 refracts light from a laser diode of the light sensor 296 toward the tissue being examined. Light reflected from the tissue surface passes back through the prism 297 to the sensor 296. The sensed returned light will be at a maximum when the beam from the beam generated by the

sensor 296 is 90° incident to the tissue surface. The mechanism described above for moving a palpation tip 218 in three dimensions can thus adjust the tip orientation to provide palpation at 90° to the breast surface.

5 A motor 300 in each laser beam positioning enclosure 294 drives a lead screw 302 that engages an arcuate gear sector 304 to rotate each sensor 296 and prism 297 about the center of rotation of gear sector 304. The laser diode within sensor 296 generates a laser beam that produces a red dot on the tissue being examined. A conventional sensor 306 within each enclosure 294 counts rotation of the lead screw 302 and is calibrated to indicate the exact distance to the surface upon which the dot appears when the beam is at 90° to the surface. The system computer then can conventionally calculate a three dimensional image of the tissue surface from a number of these angle readings.

10 Lens assembly 286, in conjunction with a light sensor 308, a pre-focused sensor lens 310 and lenses 312 operate in the same manner as a camera automatic focusing systems to bring the tissue surface into sharp optical focus by rotating the lead screw 290 as necessary. A position sensor 313 counts rotation of the lead screw 290 to provide position information to the processor 17 or some other system such as a computer. As the optical locator 16 moves ^{and focuses} ~~will focus~~ on the tissue ²⁸⁴ ~~as~~ the palpation detector 14 is brought into contact with the tissue surface.

15 Extreme position sensors 314 are preferably provided to sense movement of the lens enclosure 284 to the ends of its desired range of movement and prevent damage which might be caused by movement outside the selected range. Sensors 314 may be conventional sensors, such as electro-optical or pressure switches, which can turn off motor 288.

Multi-dimensional Imaging

20 In operation, either of the locator 16 embodiments as shown in FIG. 5 or 15 can be conventionally programmed to map an entire breast and associated tissue step by step. The horizontal and vertical (X and Y) movement of the robot arm ^(carriage) 11 position the location device 16 at selected points across the tissue under investigation. The focusing mechanism within the motor housing 282 and the lens enclosure ²⁸⁴ ~~286~~ will continually focus the sensor 308 to provide the necessary Z direction alignment. The position sensor

25

30

313 will count the revolution of the motor 288 while the motor ¹⁵ bringing the lens assembly 286 to the point of focus to continuously provide lens position information.

Once the locator 16 has visited all desired points of the tissue and a calculation is made of the distance from every desired point, the processor 17 generates a multi-dimensional image (two or three dimensions) of the tissue under investigation.

For example, during the palpation of a breast, the locator 16 verifies the location being palpated and can automatically compensate for breast movement as the patient breathes. In addition, a map of the breast is produced by a video camera 316 mounted with the locator 16 as shown in FIG. 14. Other types of mapping can be produced by means of the distance traveled by the palpation probe 92, the velocity of travel of the palpation probe 92, and the time of palpation at each contact point. For example, velocity data may be used, preferably in conjunction with the distance traveled and time data, to calculate the breast tissue density at each palpation point. Thus, the apparatus of this invention will provide an accurate map of the breast as well as detect tissue density anomalies, and provide the ability to accurately reexamine the breast from time to time to monitor any changes in breast density anomalies.

Sampling Devices

In addition, referring to ~~FIG. 17~~ ^{the alternative embodiments illustrated in Figures 16 and 17,} a sampling device 400 is provided to further examine the identified regions of tissue density anomalies in order to determine the predetermined tissue characteristics and regions such as, but not limited to, skin, fat, muscle, and abnormal tissue such as cancer. The sampling device 400 is connected to a detector 14 that is in communication with the processor 17. The sampling device 400 may be either an invasive or non-invasive device ^{(Figure 18a),} 402 such as but not limited to a needle, an aspirator, coring device, ultrasound device, temperature device, electromagnetic sensing device, or an impedance measurement device or some combination thereof. The sampling device 400 is positioned by the processor 17 at predetermined locations of the tissue under investigation. By means of three dimensional mapping produced from the tissue density data, the sampling devices may be more effectively employed to obtain additional data or even tissue samples from the tissue under investigation.

Other examples of sampling devices that may be incorporated with the invention

are shown in FIG.s 18a - 18c and include a biopsy needle and anesthetic delivery device,^{406,}
a multi-electrode sensor array 404 for examining detected tissue anomalies, a T-Scan
2000 manufactured by TransScan Research and Development Ltd. for detecting low-level
electric currents and impedance to produce a real-time image of the electrical distribution
5 within the breast, an ultrasound device, a temperature measuring device, or a liposuction
device.^{408.}

While certain specific relationships, materials and other parameters have been
detailed in the above description of preferred embodiments, those can be varied, where
suitable, with similar results. In particular, application to assess other parts of the body
10 is possible, such as, but not limited to, the face, abdomen, thighs, buttocks, etc. In these
regions as well as the breast, the apparatus and method of the current invention may be
used for the mapping of subcutaneous fat. Having created such a map of fat deposits, the
invasive sampling device as discussed above may be used for the removal of fat. In
addition, the apparatus and method of the current invention may be applied to assessing
15 the cancerous state of skin lesions.

These and other advantages of the present invention will be apparent to those
skilled in the art from the foregoing specification. Accordingly, it will be recognized by
those skilled in the art that changes or modifications may be made to the above-described
embodiments without departing from the broad inventive concepts of the invention. It
20 should therefore be understood that this invention is not limited to the particular
embodiments described herein, but is intended to include all changes and modifications
that are within the scope and spirit of the invention as set forth in the claims.

CLAIMS

What is claimed is:

1. An apparatus for detecting anomalies in tissue, the apparatus comprising:
at least one palpation probe for palpating tissue;
at least one detector for detecting the distance traveled by and the
velocity of motion of the palpation probe as it palpates the tissue;
and
a controller in communication with the palpation probe and the detector
for measuring a characteristic value of the probed tissue.
2. The apparatus according to claim 1 wherein the palpation probe is
operably connected with an electro-magnetic or electro-mechanical actuator.
3. The apparatus according to claim 1 wherein the detector includes an
optical encoder or a magnetic encoder.
4. The apparatus according to claim 1 including at least one sensor for
mapping the surface of the tissue.
5. The apparatus according to claim 1 wherein the controller produces a
dimensional mapping of the surface of the tissue.
6. The apparatus according to claim 4 wherein the at least one sensor
includes a camera, an autofocus system, a rangefinder, an acoustic sensor, or an optical
sensor.
7. The apparatus according to claim 4 wherein the at least one sensor

determines the distance from the palpation probe to the surface of the tissue.

8. The apparatus according to claim 4 wherein the at least one sensor determines the angle between the longitudinal axis of the palpation probe and the surface of the tissue.

5 9. The apparatus according to claim 1 including a second detector for measuring the color or temperature, or both, of the tissue.

10 10. The apparatus according to claim 1 wherein the controller produces a signal causing the actuator to move the palpation probe a distance, with a force, or for a time that is detected, or some combination thereof, against the surface of the tissue.

10 11. The apparatus according to claim 10 wherein the controller determines a characteristic value for the probed tissue from the detected distance, force, or time, or some combination thereof, traveled by the probe.

12. The apparatus according to claim 1 wherein the controller determines a characteristic value for the probed tissue from the detected distance traveled by the probe.

15 13. The apparatus according to claim 1 wherein the controller determines a characteristic value for the probed tissue from the detected distance traveled by the probe relative to a predetermined distance or time.

14. The apparatus according to claim 1 wherein the controller positions the palpation probe at a predetermined location against the tissue.

20 15. The apparatus according to claim 1 wherein the controller positions the longitudinal axis of the palpation probe substantially perpendicular to the surface of the tissue.

16. The apparatus according to claim 1 wherein the controller positions the palpation probe at a series of predetermined locations about the tissue.

17. The apparatus according to claim 16 wherein the series of predetermined locations encompasses the entire tissue area under investigation.

5 18. The apparatus according to claim 16 wherein the controller actuates the palpation probe at each location, and stores in a memory the location of the palpation probe, the detected distance, the velocity motion, or a characteristic value of the tissue, or some combination thereof.

10 19. The apparatus according to claim 18 wherein the controller creates a multi-dimensional model of the probed tissue using the characteristic value of the tissue.

20. The apparatus according to claim 18 wherein the controller determines a boundary using the characteristic value of the tissue.

21. The apparatus according to claim 1 including a tissue sampling device for obtaining a sample of the tissue.

15 22. The apparatus according to claim 21 wherein the sampling device is an invasive, or non-invasive device, or both.

23. The apparatus according to claim 21 wherein the sampling device is a needle, aspirator, coring device, ultrasound device, temperature sensing device, electromagnetic sensing device, or an impedance measurement device.

20 24. The apparatus according to claim 21 comprising an anesthetic delivery device to anesthetize an area proximate to the sampled tissue.

25. The apparatus according to claim 20 wherein the controller is in communication with the sampling device.

26. The apparatus according to claim 20 wherein the controller positions the sampling device at a preselected region of the tissue.

5 27. An apparatus for detecting differences in breast tissue, the apparatus comprising:

a palpation probe for palpating breast tissue;

a detector for detecting the distance traveled by or the velocity of motion of the palpation probe; and

10 a controller in communication with the palpation probe and the detector, the controller determining a breast tissue value for the probed breast tissue from the detected distance or velocity of motion.

28. The apparatus according to claim 27 wherein the palpation probe is operably connected with a solenoid.

15 29. The apparatus according to claim 27 wherein the controller positions the palpation probe at a predetermined location against the breast tissue .

30. The apparatus according to claim 27 wherein the controller applies a predetermined voltage to the solenoid to move the shaft a distance or speed determined by the resistance of the breast tissue .

20 31. The apparatus according to claim 27 wherein the detector includes an optical encoder or a magnetic encoder.

32. The apparatus according to claim 27 wherein the movement of the probe

is detected by an encoding device.

33. The apparatus according to claim 32 wherein the encoding device is an optical encoder or a magnetic encoder.

34. An apparatus for detecting differences in breast tissue, the apparatus comprising:

a detection device having a palpation probe for palpating breast tissue and a detector for detecting the distance traveled by and the velocity of motion of the palpation probe;

a location sensor for detecting the location of the breast tissue for producing an image map of the breast;

a controller in communication with the detection head and the location sensor, the controller positioning the palpation probe at a predetermined location along the breast tissue and directing the palpation probe against the breast tissue; and

a memory device for storing the distance traveled and velocity of motion of the probed breast tissue.

35. The apparatus of claim 34 wherein the location sensor includes an optical sensor.

36. The apparatus of claim 34 wherein the controller includes a microprocessor.

37. The apparatus of claim 34 wherein the location sensor is incorporated with the detection device.

38. The apparatus of claim 34 including a processor for determining a breast tissue value for the probed breast tissue from the detected distance and velocity of motion

of the palpation probe for producing a map of the breast tissue values.

39. The apparatus of claim 34 wherein the detection device includes a plurality of palpation probes.

5 40. An apparatus for detecting differences in breast tissue, the apparatus comprising a detection head having at least one palpation probe for palpating the breast tissue of a patient, and at least one detector for detecting the distance traveled by, or the velocity of motion of, or the time of motion of, said at least one palpation probe.

10 41. The apparatus of claim 40 including a location device having at least one sensor for determining the location of the breast tissue of the patient, the at least one sensor for mapping the surface of the breast tissue.

42. The apparatus of claim 41a including a controller in communication with the detection head and the location head for positioning the palpation probe at a predetermined location against the breast tissue and directing the palpation probe against the breast tissue.

15 43. The apparatus of claim 42 including a memory for storing the detected distance and velocity motion for the probed breast tissue.

44. The apparatus of claim 43 including a data processor for determining a breast tissue value for the probed breast tissue from the detected distance and velocity of motion of the palpation probe.

20 45. The apparatus of claim 44 including a breast tissue sampling device for sampling the breast tissue.

46. A method for detecting differences in breast tissue, the method comprising

the steps of:

palpating the breast tissue of a patient with a palpation probe;
detecting a distance traveled by, or a velocity of motion of, or a time in motion
of, the palpation probe; and
5 determining a breast tissue value for the probed breast tissue from the detected
distance traveled by, or the velocity of motion of, or the time in motion.

47. The method according to claim 46 wherein the palpation probe is moved
incrementally.

48. A method for detecting differences in breast tissue, the method comprising
the steps of:

- (a) positioning a palpation probe at a predetermined location against the breast
tissue of a patient;
- (b) actuating the palpation probe to move with a predetermined force against the
breast tissue;
- (c) detecting the distance traveled by and the velocity of motion of the palpation
probe;
- (d) determining a characteristic value for the probed breast tissue from at least
one of the detected distance traveled, or the velocity of motion, or both;
and
- 20 (e) storing the palpation probe location, detected distance, velocity of motion, or
breast tissue value, or a combination thereof, in a memory.

49. The method of claim 48 which comprises repeating steps (c) through (e).

50. The method of claim 48 which comprises the step of positioning the
palpation probe at an alternate predetermined location against the breast tissue and
25 repeating steps of claim 48.

51. A method for mapping differences in breast tissue values, the method comprising the steps of:

- (a) positioning a palpation probe at a predetermined location against the breast tissue of a patient;
- 5 (b) orienting a longitudinal axis of the palpation probe at substantially normal incidence to the surface of the breast tissue;
- (c) actuating the palpation probe to move with a predetermined force against the breast tissue;
- 10 (d) detecting the distance traveled by and the velocity of motion of the palpation probe;
- (e) determining a breast tissue value for the probed breast tissue from at least one of the detected distance traveled or velocity of motion; and
- (f) storing palpation probe location, detected distance, velocity of motion, and breast tissue value in a memory.

15 52. The method of claim 51 which comprises repeating steps (c) through (f).

53. The method of claim 51 which comprises the step of positioning the palpation probe at an alternate predetermined location against the breast tissue and repeating the steps of claim 51.

20 54. The method of claim 51 which comprises the step of identifying a region of breast tissue having a predetermined characteristic value.

55. The method of claim 54 which comprises the step of sampling the region of breast tissue with a sampling device.

25 56. An apparatus for detecting differences in body tissue, the apparatus comprising:

at least one palpation probe for palpating body tissue;

at least one detector for detecting the distance traveled by, or the velocity of motion of the palpation probe; and
a controller in communication with the palpation probe and the at least one detector for measuring a characteristic value of the probed body tissue.

5 57. The apparatus of claim 56 wherein the controller determines whether the body tissue detected is skin, subcutaneous fatty tissue, benign tissue, or cancerous tissue, or a combination thereof.

 58. The apparatus of claim 56 wherein the body tissue detected is located on the face, abdomen, thigh, buttocks, or body.

10 59. The apparatus according to claim 56 wherein the palpation probe is operably connected to an electro-magnetic or a electro-mechanical actuator.

 60. The apparatus according to claim 56 wherein the detector is an optical encoder or a magnetic encoder.

15 61. The apparatus according to claim 56 including at least one sensor for mapping the surface of the body tissue.

 62. The apparatus according to claim 56 wherein the controller produces multi-dimensional mapping of the surface of the body tissue.

20 63. The apparatus according to claim 61 wherein the at least one sensor includes a camera, an autofocus system, a rangefinder, an acoustic sensor, or an optical sensor.

 64. The apparatus according to claim 61 wherein the at least one sensor determines the distance from the palpation probe to the body tissue.

65. The apparatus according to claim 61 wherein the at least one sensor determines the angle between the longitudinal axis of the palpation probe and surface of the probed body tissue.

5 66. The apparatus according to claim 56 including a second detector for measuring the color or the temperature of the probed body tissue.

67. The apparatus according to claim 56 wherein the controller delivers a signal to the actuator to move the palpation probe with a predetermined force against the body tissue.

10 68. The apparatus according to claim 56 wherein the controller determines a characteristic value for the probed body tissue from the detected distance relative to a predetermined distance.

69. The apparatus according to claim 56 wherein the controller positions the palpation probe at a predetermined location against the body tissue.

15 70. The apparatus according to claim 56 wherein the controller positions a longitudinal axis of the palpation probe substantially perpendicular to the surface of the body tissue.

71. The apparatus according to claim 56 wherein the controller positions the palpation probe at a series of predetermined locations across the body tissue.

20 72. The apparatus according to claim 71 wherein the series of predetermined locations encompasses the entire body area under investigation.

73. The apparatus according to claim 71 wherein the controller actuates the

palpation probe at each location and stores in a memory the location of the palpation probe, the detected distance, the velocity motion, or a characteristic value for the probed body tissue, or a combination thereof.

5 74. The apparatus according to claim 73 wherein the controller produces a multi-dimensional model of the characteristic values of the probed body tissue.

75. The apparatus according to claim 73 wherein the controller determines a characteristic value for the probed body tissue.

10 76. The apparatus according to claim 56 including a body tissue sampling device for determining the cancerous state of the sampled body tissue.

77. The apparatus according to claim 76 wherein the sampling device is an invasive device.

15 78. The apparatus according to claim 76 wherein the sampling device is a non-invasive device.

79. The apparatus according to claim 76 wherein the sampling device is a biopsy device.

80. The apparatus according to claim 79 wherein the biopsy device is an aspiration device.

20 81. The apparatus according to claim 79 wherein the biopsy device removes a tissue sample.

82. The apparatus according to claim 81 wherein the biopsy device comprises a needle.

83. The apparatus according to claim 76 wherein the sampling device is an ultrasound device.

84. The apparatus according to claim 76 wherein the sampling device is a temperature measurement device.

5 85. The apparatus according to claim 76 wherein the sampling device is an electromagnetic sensing device.

86. The apparatus according to claim 85 wherein the sensing device comprises a sensor array.

87. The apparatus according to claim 86 wherein the sensor array measures low-level electric currents to produce an image of the electrical impedance within the body.

88. The apparatus according to claim 56 including an anesthetic delivery device to anesthetize an area proximate to the sampled body tissue.

15 89. The apparatus according to claim 56 wherein the controller is in communication with the sampling device.

90. The apparatus according to claim 56 wherein the controller determines the boundary of the detected characteristic values of body tissue.

20 91. The apparatus according to claim 73 wherein the controller determines whether the body tissue detected is skin, subcutaneous fatty tissue, benign tissue, or cancerous tissue, or a combination thereof.

92. The apparatus according to claim 56 including a liposuction device.

93. A method for mapping differences in characteristic values of body tissue, the method comprising the steps of:

- (a) positioning a palpation probe at a predetermined location against the body tissue of a patient;
- (b) actuating the palpation probe with an actuator to move with a predetermined force against the body tissue;
- (c) detecting the time traveled by, distance traveled by, or the velocity of motion of, the palpation probe;
- (d) determining a characteristic value of body tissue for the probed body tissue from at least one of the detected time traveled, distance traveled, or velocity of motion; and
- (e) storing palpation probe location, detected distance, velocity of motion, or the characteristic value of tissue, or any combination thereof, in a memory.

94. The method of claim 93 wherein the characteristic value of body tissue determined in step (d) corresponds to a predetermined characteristic value of tissue associated with a predetermined region of the body.

95. The method of claim 94 wherein the predetermined characteristic value of tissue corresponds to skin, subcutaneous fatty tissue, benign tissue, or cancerous tissue.

96. The method of claim 94 wherein the predetermined region of the body corresponds to the face, abdomen, thigh, or buttocks.

97. The method of claim 93 which comprises the step of removing tissue having a predetermined characteristic value.

98. The method of claim 97 wherein the tissue removed has a predetermined characteristic value corresponding to skin, subcutaneous fatty tissue, benign tissue, or cancerous tissue.

99. The method of claim 97 wherein the tissue is removed by means of a laser, mechanical, chemical, or cryogenic device.

100. A method for mapping differences in characteristic values of body tissue, the method comprising the steps of:

- (a) positioning a palpation probe at a predetermined location against the body tissue of a patient;
- (b) actuating the palpation probe with an actuator to move with a predetermined force against the body tissue; and
- (c) detecting the time traveled by, distance traveled by, or the velocity of motion of, the palpation probe.

101. The method of claim 100 including the step of determining a characteristic value of body tissue for the probed body tissue from at least one of the detected time traveled, distance traveled, or velocity of motion.

102. The method of claim 101 including the step of storing palpation probe location, detected distance, velocity of motion, or the characteristic value of tissue, or any combination thereof, in a memory.

103. The apparatus according to claim 4 wherein one sensor includes a digital camera and grid to establish investigation coordinates for use in comparing measurements made at some other time.

104. The apparatus according to claim 34 wherein the sensor includes a digital camera and grid to establish investigation coordinates for use in comparing

measurements made at some other time.

105. The apparatus according to claim 2 wherein the palpation probe includes an end isolator composed of an electrically insulating material.

APPARATUS AND METHOD FOR DETECTING ANOMALIES IN HUMAN TISSUE

ABSTRACT

5 This invention relates to apparatus and methods for detecting human tissues, and in particular for detecting very small anomalies such as tumors in a human breast. The invention includes tissue mapping, the detection of tissue anomalies, generating an electrical signal and graphical data corresponding thereto, and automated tissue imaging and sampling for characterizing detected tissue anomalies.

10 The invention includes apparatus and methods for detecting anomalies such as lumps and subcutaneous fat in mammal tissue by means of computer-controlled palpation. The apparatus and methods includes detection device capable of movement in three dimensions over a selected portion of the body. The detection device includes a palpation probe that is brought into contact across the selected portion of the body, palpating each selected portion in a sequence of movements to measure relative differences in tissue density. The apparatus also includes a scanning device for mapping the selected portion of the body, detecting tissue color, or detecting temperature. The apparatus also includes a locator device for positioning the detector or scanning device for accuracy and repeatability of palpation and scanning over a series of periodic investigations. The apparatus also includes a sampling device for obtaining tissue
15
20 samples from the selected tissue that may be used to characterize the cells of the selected tissue.

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**APPARATUS AND METHOD FOR DETECTING
ANOMALIES IN HUMAN TISSUE**

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REFERENCE TO RELATED APPLICATION

This application claims priority to U.S. Patent Application Ser. No. 09/241,193 entitled "Apparatus for Detecting Very Small Breast Anomalies" filed on February 1, 1999, which is incorporated herein in its entirety by reference.

FIELD OF THE INVENTION

This invention relates to apparatus and methods for detecting human tissues, and in particular for detecting very small anomalies such as tumors in human tissue such as a breast. The invention includes tissue mapping, the detection of tissue anomalies, generating an electrical signal and graphical data corresponding thereto, and automated tissue imaging and sampling for characterizing detected tissue anomalies.

BACKGROUND OF THE INVENTION

The early detection of anomalous human tissue, and in particular detection of undesirable tissue such as fat, fibrous tumors, or cancerous tissue is a much felt need. For example, recent findings indicate that one out of eight women will develop breast cancer, the second leading cause of death in women. The earliest indication of breast cancer generally is the occurrence of a painless lump, sometimes associated with nipple discharge and skin retraction. Unfortunately, later, more obvious and less survivable indications of cancer are generally due to metastases to bone, brain, lungs and liver. Accordingly, early detection of anomalous tissue and tissue changes is essential for improvement of survivability and effective treatment. Attempts at early detection through monthly self-examinations and mammography have proven beneficial but have

not satisfied the need for more effective methods of early detection and corresponding treatment.

By way of example, if small lumps, less than 20 mm, can be detected early they can then be diagnosed by a biopsy and treated should the lump be found to be malignant. Accordingly, early detection would allow for less invasive treatment such as a lumpectomy with possible radiation treatment of axillary nodes making less likely the need for a modified radical mastectomy with axillary node dissection. In addition through early treatment, the five-year survival rate maybe improved by as much as 85 percent. Absent early detection, distant metastasis are likely reducing survival rates to 10 percent or even less. The present invention address this very critical need.

Although early detection is essential, it can be difficult to achieve even by skilled physicians. Monthly self examinations have been shown to be helpful, particularly when followed by the examination of a physician in the event something is detected. It is, however, difficult and often unlikely for an unskilled person to do a thorough examination or detect very small lumps.

Presently, anomalies in tissue like the breast are detected mostly by periodic palpation by the hand of a physician or radiographic mammography. To be effective, however, hand palpation must be frequent, particularly in older women in order to detect tumors before they can metastasize. Unfortunately the subjective nature of hand palpation and the frequency required to make these examinations effective are often tremendous limitations that render palpation examinations ineffective due to convenience, availability, and cost. In addition, mammography is also troublesome due to the concern of accumulated radiation exposure from too frequent mammograms. It is also known that mammography, unlike palpation, can be limited as it may not detect very small tumors, particularly in the denser breast tissue of younger women.

In addition to anomalies, it is also very important that changes in tissue structures be detected and monitored over time. The problem, therefore, is how to detect minor changes in tissue. For example, hand palpation of issue may not reveal very small changes and anomalies within breast tissue until the tissue changes are so large or the anomalies so prominent that they can be detected and no longer responsive to early

treatment.

Another problem limiting the effectiveness of hand palpation is that it is not possible to record, retain and at a later time recall historical data of prior detected anomalies, including their location and the nature of the changes over time. This is particularly the case for soft anomalous tissue that is located further from the surface of the skin with diameters that are less than 10 mm. It is also known that anomalies deeper in the tissue of large breasts are particularly difficult to detect by hand palpation. Even if detected, it is often not possible to characterize the tissue or changes in the tissue due to the subjective nature and lack of standards for hand palpation which almost entirely depends on the skill and sensitivity of the examining physician.

Accordingly, the present invention address each of the aforementioned problems and urgent needs in the art for improved apparatus and methods for early detection of tissue anomalies and changes in tissue structures, particularly very small anomalies in breast tissue, as well as the urgent need to objectively determine tissue characteristics and produce, maintain, and compare tissue mapping and images of the tissue and its characteristics over time.

SUMMARY OF THE INVENTION

The present invention is an apparatus and method for detecting anomalies in human tissue. In one embodiment of the invention, the apparatus and method includes palpation by at least one palpation device for palpating tissue such as a human breast tissue and detection by at least one detector for detecting the time, distance traveled by, and the velocity of motion of the palpation probe. The apparatus and method includes measurement by a controller in communication with the palpation device and the detector for measuring a predetermined diagnostically relevant tissue characteristics from the probed breast tissue.

In one embodiment of the invention, the apparatus automatically scans, maps, and palpates an entire breast in a continuous manner, and compares adjacent tissue densities in order to detect changes in the physical characteristics of the breast tissue. Tissue density is measured across the entire breast and differentiated by means of relativistic or historic data in order to detect tissue changes and anomalies including their location and

size. Further, the invention records, retains and recalls historical data of the detected anomalies and detected tissue characteristics for comparison and mapping of the data, including anomaly location and changes over time. Although breast tissue is used as an example of the tissue under investigation throughout this disclosure, it is to be understood that any tissue structure can be palpated and characterized by this invention.

In another embodiment of the invention, the apparatus includes a platform on which a patient is positioned in a consistently similar manner each time the patient is tested. The platform is controlled by a location device such as an optical or video detector. A detection device such as a palpation probe is mounted on a carriage for movement in at least three directions adjacent to the patient. The location device continuously positions the patient so that the detection device can measure the tissue characteristics of the selected tissue under investigation.

The palpation device includes at least one probe or finger-like palpation end movable toward and away from the surface of the selected tissue in order to palpate the breast in the same general manner as a physician. The palpation device includes a probe that is maintained perpendicular to the selected tissue and movable across the entire surface of the selected tissue or beyond.

Information sensed by the palpation device is collected, stored and displayed in a manner that will show details of detected anomalies for comparison with historical data, and so that further testing, including automated biopsy and treatment, if required, can be performed. For example, a sampling device such as a biopsy needle or an aspiration device may be incorporated with the invention. Alternatively, the sampling device may also include devices such as an electromagnetic sensing device, temperature measuring device, or an ultrasound device. In addition, the invention may be used to treat a patient by directing radiologic, chemotherapeutic treatments, or even surgical instruments that are directed by, or attached to the movable arm provided by, the invention.

Although the invention may be used to characterize breast tissue, it is understood that the invention may be used to characterize any tissue such as, but not limited to, the face, abdomen, thighs, and buttocks, which may be measured by palpation to measure and locate tissue structure such as subcutaneous fat. Further, detected regions of fat can

be located and removed by the invention by a liposuction device that is directed by the invention. In addition, the invention may be used to palpate and detect lesions of the skin.

BRIEF DESCRIPTION OF THE DRAWINGS

5 For the purpose of illustrating the invention, there is shown in the drawings a form which is presently preferred; it being understood, however, that this invention is not limited to the precise arrangements and instrumentalities shown.

Figure 1 is an illustration of a detection device for detecting anomalies in human tissue according to the present invention.

10 Figure 2 is an illustration of a patient positioning platform for use with the detection device shown in Fig. 1.

Figure 3 is an illustration of a detection head and actuator according to the present invention.

15 Figure 4 and 4A illustrate a position and movement measurement device used with the detection head and actuator shown in Fig. 3.

Figure 5 is an illustration of a locator head assembly according to the present invention.

Figure 6 is an illustration of a vertical positioning mechanism for use with a detection device.

20 Figures 7-10 illustrate alternate embodiments of a detection head according to the present invention.

Figure 11 illustrates a palpation tip for a detection head according to the present invention.

25 Figure 12 illustrates a detection head having a plurality of parallel palpation tips according to the present invention.

Figures 13a-13b illustrate an actuator with an encoder according to the present invention.

Figure 14 illustrates an optical locating head and detection head mounted to a carriage according to the present invention.

30 Figure 15 illustrates the internal components of an alternate embodiment of a

locator head assembly according to the present invention.

Figure 16 illustrates a detection head and actuator having a sampling device according to the present invention.

Figure 17 illustrates an optical locating head and detection head having a sampling device mounted to a carriage according to the present invention.

Figures 18A-18C illustrate alternate embodiments of sampling devices according to the present invention.

DETAILED DESCRIPTION OF THE INVENTION

Referring now to the drawings, wherein like numerals indicate like elements, there is shown in FIG. 1 an illustration of one embodiment of an apparatus 10 for detecting anomalies in human tissue according to the present invention. In one aspect of the invention, the apparatus 10 includes a carriage (also referred to as a robot arm) 11 that is mounted at a proximal end to a horizontal support 12 for movement therealong, and a detector 14 (also referred to as a detection head) that is mounted at the distal end of the carriage 11. The detector is shown in more detail in FIG.s 3 and 4 and is used to detects the characteristics of tissue by palpation. A locator 16, for locating the position of a patient relative to some reference, is mounted to the detector 14 for movement therewith. Data is produced by the palpation device and collected, stored and displayed in a manner that will capture details of the detected anomalies for comparison with historical data. The invention provides data about the tissue under investigation by means of an automated biopsy and treatment by means of surgical attachments for the delivery of radiologic, chemotherapeutic, or laproscopic surgery.

For example, the digital information can be received, stored, processed or displayed in a similar manner to existing medical devices such as a CAT scan or MRI. In addition, the invention can produce multi-dimensional images that may be viewed on conventional computer monitors. Images may be produced using color to indicate areas of differing tissue density. These images may be further enhanced by combining tissue density information with tissue color and temperature information to detect and track even smaller tumors in discrete tissue areas.

Horizontal Movement

In another embodiment of the invention, which is shown in detail in FIG. 6, the detector 14 is positioned over the patient and provided with horizontal movement by means of a horizontal support 12 that is mounted on a vertical support mechanism 18, allowing the horizontal support 12 to move in a vertical direction. The horizontal support 12 includes a traveler 20 that rides on bearings 22 along rods or tubes 24 that are secured at their ends to end blocks 26,28. A lead screw 30 is driven by a drive motor 34 and extends between a pair of end blocks 26,28 and bearings 32. Lead screw 30 extends through correspondingly threaded openings 36 of the traveler 20 so that the traveler 20 will move to the right or left as the lead screw is rotated in one direction or the other, and limit switches 37 are used to prevent over travel of the traveler 20. Guide rods 38 extend vertically through the end blocks 26,28 so that the horizontal support 12 can be moved vertically by means of a lead screw 40 that extends vertically through one end block 28.

The carriage 11 includes a base 42 secured to the traveler 20. A motor 44 within the base 42 rotates a screw 46 that is threaded into an intermediate body 48 to raise and lower that body as the screw 46 is rotated one way or the other. A pair of guide rods 50 extend through a bracket 52 to guide movement of the intermediate body 48. A lower body 54 is secured to the intermediate body 48 for rotation relative thereto. A motor 56 is mounted on the intermediate body 48 with the lower body 54 mounted on the motor shaft 56 for rotation with the shaft 56.

Vertical Movement

The detector 14 is positioned over the patient and provided with vertical movement by means of a mechanism for raising and lowering the entire carriage 11 is shown in FIG. 6. The carriage 11 is supported by a pair of vertical guide rods 38 that extend from a sturdy base 156 to a top plate 158. A pair of end blocks 26,28 support the horizontal support 12 and provide vertical movement therealong.

A motor 160 rotates a sturdy lead screw 162 threaded through a block 28. An upper limit switch 164 and a lower limit switch 166 prevent movement of the horizontal support 12 beyond desired limits. For a very strong, sturdy assembly, the base 156 will rest on the floor or a sub-floor so that the platform assembly 64 could be positioned

within the frame formed by the base 156, the top support 158 and the guide rods 38.

Positioning Arm

5 An arm 61 is pivotally mounted at a pivot 62 on a bracket 64 that is mounted on the distal end of the lower body 54. A motor 60 on the lower body 54 drives a pulley 62 on the arm 61 through a jackshaft 64. Thus, the entire carriage 11 can be moved horizontally by the horizontal the support 12, and vertically by the vertical support 18. The lower body 54 of the carriage 11 can be rotated 360°. The arm 61 carries the detector 14 which can be pivoted through at least 120°. The arm 61 can also carry and operate other devices such as, but not limited to, attachments for the delivery of acoustic, radiologic, chemotherapeutic treatments or laparoscopic surgery. The combination of movements just described, permit the detector 14 to be positioned in any desired position relative to any portion the surface of human body, particularly a breast.

10 Although a particular positioning arrangement of the detector 14 has been described, it is understood that the invention can include any type of positioning system that will provided several degrees of freedom of movement for the detector 14 or other devices.

Position and Location System

15 In one embodiment of the invention, an investigation of a selected body part or region is started by positioning the patient on a platform (also referred to as a bed) 62 that is affixed to a position adjusting assembly 64 such as that shown in FIG. 2. The platform 62 is typically positioned below the detector 14 of FIG. 1. The platform 62 has a comfortably padded upper surface and a matrix board 66 with a location pattern 67, that is typically positioned adjacent to the shoulders of the patient 68.

20 The matrix board 66 and pattern 67 are used to maintain registration between the specific points of the patient's body under investigation and the acquired measured data. In addition, the matrix board 66 and pattern 67 are used to maintain registration between subsequent measurements taken at different times for the same patient 68.

25 For example, optical measuring means such as, but not limited to, a video camera, a fiducial reference target, or a laser location device can be used to locate the exact position of the patient or selected body parts such as arms, shoulders and neck

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relative to the matrix board 66 and its pattern 67 during an investigation.

In subsequent investigations, the patient 68 is positioned on the platform 62 at a later time, and the optical system, and with or without the aid of adaptive software techniques, the invention will correlate prior and presently collected location data measurement data with multiple prior measurements. Further, movement by the patient 68 that may introduce errors in the measured data can be corrected during the investigation by error correction techniques provided by the optical system. Although it is desirable for the patient 68 be placed in the same position for each investigation, it is not required since that the invention can correct for any change in position by means of position reference data collected during each periodic investigation.

Referring to FIG. 2, the underside of platform 62 includes conventional tubular bearings through which a pair of horizontal guide rods 70 pass. A central threaded rod 72, driven by a motor 76, engages end bearings 74. As the motor 72 rotates the platform 62 is moved right to left. The platform 62 is similarly moved up and down by means of a pair of guide rods 78 secured to end walls 80 of assembly 64 and driven by a motor 84 that rotates a threaded rod 82 which moves the platform 62 as desired.

The invention provides a means to control the position of the patient for consistent reinvestigation. This is accomplished by means of the platform 62 and a location device (also referred to as a sensor or a head) 16 which is shown in FIG. 5. The location device 16 provides accurate location information for positioning the patient 68 on the platform 62 or for correlating the data with subsequent or prior measurements by means of geometric translation which can be achieved by pattern recognition or reference to a fixed fiducial reference.

For example, a digital camera 134 may be used to produce a digitized image of the tissue under investigation. The image may then be compared by a computer system or technician to prior or subsequent images. A white light source 136 may also be used to produce a three dimensional image. As shown in FIG. 5, the light source 136 is employed with an auto-focus system having a lens 138, and a lead screw 140 rotatable by a motor 142 and threaded through a lens mount bracket 144 for focusing a light spot on the surface of the tissue under investigation. The spot of light is moved transversely

and focused at different depths along the tissue surface. Data of the focus position of the lens 138 is collected and used to produce a three dimensional image of the tissue surface.

In another aspect of the invention as shown in FIG. 5, a laser scanner 146 may be used to create a three-dimensional image. The laser scanner 146 includes a laser emitter 148 and a focusing system 150 for producing a focused laser spot on the surface of the tissue under investigation. For example, a laser operable in the range of 680-820 nm with a power level about 0.0095 should provide sufficient laser power to produce an image without damaging the tissue under investigation.

In all aspects of the invention, prior and subsequently collected image data can be used to translate position data of the tissue under investigation. This feature provides enhanced capabilities in the examination of anomalies in the tissue under investigation. For example, a three-dimensional image can be divided into a matrix of cubes or slices with geometric indicia (e.g., a cube might be identified as cube 2,4,9 on an x-y-z axis basis) and locations can be directly compared between the light spot image and the probe palpation locations.

Palpation Systems

One embodiment of the detector 14 according to the present invention is shown in FIG. 3. The detector 14 is shown with a removable connection 86 for attachment onto a rotatable arm 61. The detector 14 has a palpation probe housing 90 for supporting a palpation probe or finger 92 and a sensor 94. The sensor 94 includes, but is not limited to, a device for sensing distance, acoustic waves, x-rays, MRI, color, and temperature. The sensor 94 may also be mounted to the detector's main housing 87. The palpation probe 92 is designed to simulate a physician's finger during a palpation investigation like that in a manual breast examination. In a preferred embodiment, the palpation probe 92 is composed of a disposable material, such as, but not limited to, glass or plastic.

Distance is measured by means of a sensor 94, which is an autofocus system like that used in cameras. The auto-focus system can provide precise data such as the distance between the breast surface and a known reference point within the sensor. In another aspect of the invention, a plurality of spaced range finders can be used to measure the angle with respect to the breast surface so that the orientation of the palpation probe

92 is maintained at a pre-determined angle such as, but not limited to a, perpendicular to the tissue under investigation.

Color is sensed by a color sensing device such as a photo-detection diode or spectrum detection sensor. In addition, a prism or diffraction grating for dispersing incoming light and refracting each color of light to an independent photoelectric sensor may also be used.

Referring to FIG. 3, one aspect of the invention the palpation probe 92 is secured to the distal end of a first shaft 100 which is slidably connected to the housing 90 and pivoted, at its proximal end, to the distal end of a first arm 102 at a pivot point 104. The first arm 102 is rotatable about an axis 106 that is centrally located along a second arm 98. The proximal end of the first arm 102 is pivotally connected to a drive shaft 108 at a second pivot point 110. When the drive shaft 108 is moved axially by an actuator located within an actuator housing 112, which is shown in detail in FIG. 4, the first shaft 100 and the palpation probe 92 move a proportional distance in the opposite direction.

The motion of the palpation probe 92 is then measured to determine time, distance traveled, velocity, and resistance encountered by the probe 92 as it comes in contact with the tissue under investigation. For example, an optical reading device 126 having a laser source is located in a reader housing 114 for detecting movement of the palpation probe 92 by means of an optical encoded gradient 113 attached to the drive shaft 108. The parameters of time, distance traveled, and rate thereof, are used to determine a characteristic value of the tissue under investigation in response to the feedback resistance experienced by the palpation probe 92 when it is pressed against the tissue under investigation.

To further improve the accuracy of the measurements, a position error correction sensor 116 is used in cooperation with a position detection member 119 such as, but not limited to, an optical gradient, inertial displacement device or motion sensor, that is attached to the first shaft 100 to detect and correct positioning errors. The position error correction sensor 116 is used to correct movement and position errors of the components of the detector 14. Movement of the palpation probe is accomplished by the activation of a first coil 118 which is shown in detail in FIG. 4. Slight changes in position of the

tissue under investigation like that caused by breathing, can be sensed by the palpation probe and a corresponding position correction signal that is sent to selected coils of the first coil 118 to correct displacement errors.

In one embodiment of the invention, the palpation probe 92 is moved by a series of electromagnetic coils 118 that are arranged in a puniformly spaced relationship along a central tube 120. In a preferred configuration, the electromagnetic coils 118 may be formed as a continuous helix to from a solenoid. An end shaft 122 is axially secured to the proximal end of the drive shaft 108 and extends into a tube 120.

An end shaft 122 is formed from a magnetic material so that when the coils 118 are actuated sequentially, beginning with the coil adjacent to the end shaft 122, the magnetic forces in the coils 118 will pull the end shaft 122 into the tube 120. Alternately, the coils 118 are actuated individually in a sequence or by applying incrementally increasing voltages to the coils 118. The extension of the drive shaft 108 is controlled by the movement of the end shaft 122 which can be adjusted by a threaded mechanism 128. The maximum excursion of the drive shaft 108 is limited by a pin 130 extending from the drive shaft 108 and a pair of limit switches 132.

The magnetic force applied is sufficient to advance the palpation probe 92 to compress the tissue under investigation but not enough to cause discomfort or damage to the tissue. The time and distance the probe advances will be in proportion to the density of the tissue, resulting in less time and movement for dense tissue and more time and movement for less dense tissue.

In operation, the first coil 118 is actuated to move the palpation probe 92 a predetermined force, distance, time, or some combination thereof. The first coil 118 is energized in a step-wise fashion at about 250mv increments from 0 to 10 volts, and the change in force is about 10 grams per mm² per step. When the probe fails to move a predetermined distance for a predetermined time, additional force is applied by means of the second coil 118. It is to be understood that additional coils similarly operated, can be added as required.

The resistance characteristic of the tissue under investigation is determined as when the applied pressure, distance traveled or time of pressure reaches a predetermined

value. The parameters of force, distance or time are measured at the predetermined value and the parameter information is then transferred to information storage means and/or to a controller for processing, analysis, and the production of multi-dimensional images.

In one aspect of the invention, the palpation information including, but not limited to, distance, force, time, resistance, and characteristic value of the tissue under investigation, are obtained by encoding and transmitting the acquired palpation information. As shown in FIG. 4, a laser optic card 124 associated with the shaft 108 is read by a laser card reader 126 which transmits the encoded information to a storage device or the controller 17 for processing. The controller then processes the information as required for use by other devices or in a manner similar to a CAT systems or equivalent devices.

An example of a laser card 124 that is to be used with the laser card reader 126 is shown in FIG. 4a. The card 127 has a series of reflecting areas 129 that are separated by non-reflective areas 131. The non-reflecting areas 131 of the card 127 can be light absorbing or transparent. A laser transmitter 133 directs a laser beam 135 against the patterned area of the laser card 124. When the laser beam 135 hits a reflecting area, reflected light is picked up by a receiver 137. As the card 124 is moved in a direction transverse to the reader 126, the pattern of reflected pulses are counted to measure movement of the drive shaft 108 and the palpation probe 92. The reflecting areas can be as small as about 0.001 mm for more precise measurements of the motion of the palpation probe 92. Although only laser illumination has been discussed, it is to be understood that any form of illumination can be applied including, but not limited to, visible, infrared, or ultraviolet light, which may, or may not, be coherent, focused, columnated or diffused.

Palpation Actuators and Probes

In another aspect of the invention, a palpation detector for detecting changes in density of tissue is shown in FIG. 7. A permanent magnet 200 is mounted on a non-magnetic rod 202 that is movable along the axis of the rod centerline. Suitable guides 204 such as rollers, ball bearings, a sleeve or the like are provided for smooth, low resistance, axial movement of the rod 202. The permanent magnet 200 is proximate to

an electromagnetic coil head 206 mounted on a shaft 207 and fixed to a housing 208. The permanent magnet 200 and the electromagnet head 206 have common poles while the rod 202 has an opposing pole 210. Electromagnet head 206 is powered by any suitable number of powered coils 212 that are connected at a terminal 214 to a power source by supply wires 216. The magnets having common poles they will oppose each other pushing the magnets apart when the electromagnet coils 212 are activated. The intensity of the opposing force is adjusted by the number of coils 212 and the level of power applied thereto.

A palpation probe tip 218 is shown in FIG. 11, according to the present invention. The palpation probe tip 218 is mounted on the distal end of the rod 202 which is brought into contact with (or to a predetermined distance from) the tissue under investigation such as a breast surface by the positioning arm 11. The coil 212 is energized to increase the field around a shaft 207 to increase the field at the electromagnetic head 206 in order to force the permanent magnet 200 further away from the electromagnetic head 206, which moves the palpation probe tip 218 against the tissue. The tissue is depressed at the point of contact which transfers the tissue's elasticity characteristic in the form of a back pressure through the probe tip 218 and rod 202 and onto the coil 206.

The amount of back pressure applied including variations thereof are measured by recording instrumentation associated with the processor 17. It is to be understood that this pressure measurement system can be incorporated with any palpation device disclosed herein. Additional embodiments of palpation detection and actuator devices are shown in FIG.s 8 - 14.

The detection and actuator device shown in FIG. 8 includes a permanent magnet 222 that is mounted at one end to an actuator rod 224 which is supported by a slidable sleeve 226 that is mounted on a housing 228. A tip 218 of the sort shown in FIG. 11 is secured to the other end of rod 224. A second permanent magnet 230 is mounted on a holder 231 that is coaxial with the rod 224. The permanent magnets 222,230 are selected with common poles (north to north or south to south.) The holder 231 is supported on a disk 232 that is slidable within the housing 234 and coaxial with the rod 224. A sleeve 236 is preferably mounted on the holder 231 to aid in guiding the movement of the rod

224.

FIG. 11 shows a preferred embodiment of a palpation tip configuration 218. The tip configuration 218 includes a rounded endpiece 254 for contact with the tissue under investigation. Any suitable material may be used that can be inexpensively cleaned and made safely disposable is preferred. An end isolator 256, made up of an electrically insulating material is used to prevent static electricity discharge of the tissue. A core member 258 connects the endpiece 254 to a base 260 which is secured in any suitable manner, such as threads, to the rod 224.

In operation, the detector 14 is moved as discussed above to bring the palpation tip 218 into proximity with a selected location along the tissue under investigation. When the palpation tip 218 is initially brought into proximity to the breast surface, gravity causes the rod 224 and the permanent magnets 222 to move apart. A motor 238 mounted in a housing 234 drives a lead screw 240 which is threaded through a corresponding female thread 242 in a disk 232. The motor 238 may be any suitable motor, such as a low rpm DC motor or a stepper motor. Rotation of the lead screw 240 will move magnet 230 towards magnet 222 decreasing the intermagnet gap until the tissue resistance returns the intermagnet gap to a predetermined distance. The displacement of the holder 231 and the disk 232 is related to the tissue density characteristics of the tissue at the contact point. A sensor 247 counts the revolutions of the motor 238 to measure the corresponding degree of movement of the palpation tip 218 into the tissue.

Conventional safety sensors 244 may be provided to limit maximum movement of disk 232 (and movement of tip 218 in accordance with disk position) to prevent damage to the breast. As mentioned above, the magnetic field between the magnets 222, 230 will act as a resilient mount for the palpation probe tip 218, limiting any damage or injury should the tip strike a breast or other surface.

FIG. 9 shows another embodiment of a detector 14 having a pair of housings 228, 234, an actuator rod 224, sleeves 226, 236, a palpation tip 218, a holder 231, a disk 232, a motor 238, and sensors 242, 244. Instead of spaced permanent magnets 222, 236 a spring 248 is fastened between the proximal end of the rod 224 and the holder 231. The

spring 248 is selected to provide a bias to the two juxtaposed ends of the rod 224 and the holder 231 to a particular, predetermined spacing. When the detector 14 is positioned over the tissue the palpation tip 218 extends downwardly under the force of gravity. The motor 238 rotates to move the disk 232 and holder 231 toward the rod 224 until the gap between the distal end of the holder 231 and the proximal end of the rod 224 is at the original predetermined distance. The total movement of the holder 231 is indicated by the number of revolutions of the lead screw 240 as measured by the counting sensor 242, which is indicative of the desired tissue characteristic.

Another aspect of a detector 14 is shown in FIG. 10 having a gas 250 interface that is enclosed within a sleeve 236 at the proximal end of a rod 224. The sleeve 236 fits over the rod 224 in a sealing arrangement to prevent the pressurized gas 250 from escaping. Any suitable conventional seals may be used between the rod 224 and the sleeve 236.

The axial force applied to the rod 224 will change the gas pressure within the sleeve 236 which will be measured by a pressure sensor. When placed in contact with the tissue under investigation, the contact pressure is sensed by the amount of pressure applied to the gas by the palpation probe 218. Pressure in the sleeve is adjusted by the rotation of the motor 238 which is counted by sensor 242. The amount of pressure applied by the rotation of the motor 238 is proportional to the desired tissue characteristic such as hardness and density.

FIG. 12 shows another detector 11 having a plurality of palpation probe tips 218 that are arranged in a parallel array and mounted on a corresponding number of actuator rods 262 for axial movement. In one aspect of the detector 11, a plurality of offset extension connectors 264 made of inflexible cables are used to transmit motion by means of transducers 266 that are connected to the output ends of the rods 262. An optical encoder and reader system 268 is incorporated to measure the movement of each palpation tip 218 during palpation of the tissue under investigation.

FIG.s 13a and 13b show two embodiments of the encoder and reader system 268 having a plurality of detectors 276 and encoder cards 272. The encoder system 268 includes an encoder slide 270 that is secured to a rod 224. The encoder slide 270 is

secured to any suitable part of the rod 224 or to a palpation tip 218, as desired. The encoder slide 270 is transparent and includes a strip 272 with reflective dots 274 (or, in the alternative transparent dots in an otherwise opaque strip 272).

Decoder sensors 276 mounted on a housing 278 are provided on opposite sides of the encoder slide 270 and secured to a housing 228 by any suitable mounting means. The decoder sensors 276 are optical or laser sensors having light emitters of the sort used to read compact disks. The dots 274 are reflective particularly against a transparent background which causes light to pass between the pair of light transmitting decoder sensors 276. As the encoder slide 270 is moved, light from the emitters is either reflected by the reflective dots 274 or transmitted through the disk and onto the sensor 276.

Accordingly, the detected light indicates movement of the slide and the number of pulses of light received which are used to measure the distance of movement of the rod 228 and the palpation tip 229. Alternatively, when the dots 274 are transparent against an opaque background, light pulses received at the detector decoder sensor 276 will indicate the distance of movement of the rod 228 and the palpation tip 229. FIG. 14 shows another embodiment of the detector 14 in which the optical locating head 16 and detector 14 are both mounted at the end of the arm on carriage 11.

FIG. 15 shows an optical locator 16 having a motor housing 282 in combination with a detector 16. A lens enclosure 284 is secured to the motor housing 282 after precise positioning during manufacture of the assembly. A lens assembly 286 is slidably mounted within lens enclosure 284 for axial movement relative thereto. A motor 288 is mounted within motor housing and drives a lead screw 290 which is threaded through a nut 292 secured to lens assembly 286 to move the lens assembly axially within lens enclosure 284.

Two laser beam positioning enclosures 294 are mounted on opposite sides of motor housing 282. Each enclosure 294 contains a pre-focused conventional (typically 680 to 850 nanometer) laser diode and light sensor 296. A prism 297 refracts light from a laser diode of the light sensor 296 toward the tissue being examined. Light reflected from the tissue surface passes back through the prism 297 to the sensor 296. The sensed returned light will be at a maximum when the beam from the beam generated by the

sensor 296 is 90° incident to the tissue surface. The mechanism described above for moving a palpation tip 218 in three dimensions can thus adjust the tip orientation to provide palpation at 90° to the breast surface.

5 A motor 300 in each laser beam positioning enclosure 294 drives a lead screw 302 that engages an arcuate gear sector 304 to rotate each sensor 296 and prism 297 about the center of rotation of gear sector 304. The laser diode within sensor 296 generates a laser beam that produces a red dot on the tissue being examined. A conventional sensor 306 within each enclosure 294 counts rotation of the lead screw 302 and is calibrated to indicate the exact distance to the surface upon which the dot appears when the beam is at 90° to the surface. The system computer then can conventionally calculate a three dimensional image of the tissue surface from a number of these angle readings.

10 Lens assembly 286, in conjunction with a light sensor 308, a pre-focused sensor lens 310 and lenses 312 operate in the same manner as a camera automatic focusing systems to bring the tissue surface into sharp optical focus by rotating the lead screw 290 as necessary. A position sensor 313 counts rotation of the lead screw 290 to provide position information to the processor 17 or some other system such as a computer. As the optical locator 16 moves will focus on the tissue as the palpation detector 14 is brought into contact with the tissue surface.

15 Extreme position sensors 314 are preferably provided to sense movement of the lens enclosure 284 to the ends of its desired range of movement and prevent damage which might be caused by movement outside the selected range. Sensors 314 may be conventional sensors, such as electro-optical or pressure switches, which can turn off motor 288.

Multi-dimensional Imaging

20 In operation, either of the locator 16 embodiments as shown in FIG. 5 or 15 can be conventionally programmed to map an entire breast and associated tissue step by step. The horizontal and vertical (X and Y) movement of the robot arm 11 position the location device 16 at selected points across the tissue under investigation. The focusing mechanism within the motor housing 282 and the lens enclosure 286 will continually focus the sensor 308 to provide the necessary Z direction alignment. The position sensor

25

30

313 will count the revolution of the motor 288 while the motor bringing the lens assembly 286 to the point of focus to continuously provide lens position information.

Once the locator 16 has visited all desired points of the tissue and a calculation is made of the distance from every desired point, the processor 17 generates a multi-dimensional image (two or three dimensions) of the tissue under investigation.

For example, during the palpation of a breast, the locator 16 verifies the location being palpated and can automatically compensate for breast movement as the patient breathes. In addition a map of the breast is produced by a video camera 316 mounted with the locator 16 as shown in FIG. 14. Other types of mapping can be produced by means of the distance traveled by the palpation probe 92, the velocity of travel of the palpation probe 92, and the time of palpation at each contact point. For example, velocity data may be used, preferably in conjunction with the distance traveled and time data, to calculate the breast tissue density at each palpation point. Thus, the apparatus of this invention will provide an accurate map of the breast as well as detect tissue density anomalies, and provide the ability to accurately reexamine the breast from time to time to monitor any changes in breast density anomalies.

Sampling Devices

In addition, referring to FIG. 17, a sampling device 400 is provided to further examine the identified regions of tissue density anomalies in order to determine the predetermined tissue characteristics and regions such as, but not limited to, skin, fat, muscle, and abnormal tissue such as cancer. The sampling device 400 is connected to a detector 14 that is in communication with the processor 17. The sampling device 400 may be either an invasive or non-invasive device 402 such as but not limited to a needle, an aspirator, coring device, ultrasound device, temperature device, electromagnetic sensing device, or an impedance measurement device or some combination thereof. The sampling device 400 is positioned by the processor 17 at predetermined locations of the tissue under investigation. By means of three dimensional mapping produced from the tissue density data, the sampling devices may be more effectively employed to obtain additional data or even tissue samples from the tissue under investigation.

Other examples of sampling devices that may be incorporated with the invention

are shown in FIG.s 18a - 18c and include a biopsy needle and anesthetic delivery device, a multi-electrode sensor array 404 for examining detected tissue anomalies, a T-Scan 2000 manufactured by TransScan Research and Development Ltd. for detecting low-level electric currents and impedance to produce a real-time image of the electrical distribution within the breast, an ultrasound device, a temperature measuring device, or a liposuction device.

While certain specific relationships, materials and other parameters have been detailed in the above description of preferred embodiments, those can be varied, where suitable, with similar results. In particular, application to assess other parts of the body is possible, such as, but not limited to, the face, abdomen, thighs, buttocks, etc. In these regions as well as the breast, the apparatus and method of the current invention may be used for the mapping of subcutaneous fat. Having created such a map of fat deposits, the invasive sampling device as discussed above may be used for the removal of fat. In addition, the apparatus and method of the current invention may be applied to assessing the cancerous state of skin lesions.

These and other advantages of the present invention will be apparent to those skilled in the art from the foregoing specification. Accordingly, it will be recognized by those skilled in the art that changes or modifications may be made to the above-described embodiments without departing from the broad inventive concepts of the invention. It should therefore be understood that this invention is not limited to the particular embodiments described herein, but is intended to include all changes and modifications that are within the scope and spirit of the invention as set forth in the claims.

CLAIMS

What is claimed is:

1. An apparatus for detecting anomalies in tissue, the apparatus comprising:
at least one palpation probe for palpating tissue;
at least one detector for detecting the distance traveled by and the
velocity of motion of the palpation probe as it palpates the tissue;
and
a controller in communication with the palpation probe and the detector
for measuring a characteristic value of the probed tissue.
2. The apparatus according to claim 1 wherein the palpation probe is
operably connected with an electro-magnetic or electro-mechanical actuator.
3. The apparatus according to claim 1 wherein the detector includes an
optical encoder or a magnetic encoder.
4. The apparatus according to claim 1 including at least one sensor for
mapping the surface of the tissue.
5. The apparatus according to claim 1 wherein the controller produces a
dimensional mapping of the surface of the tissue.
6. The apparatus according to claim 4 wherein the at least one sensor
includes a camera, an autofocus system, a rangefinder, an acoustic sensor, or an optical
sensor.
7. The apparatus according to claim 4 wherein the at least one sensor

determines the distance from the palpation probe to the surface of the tissue.

8. The apparatus according to claim 4 wherein the at least one sensor determines the angle between the longitudinal axis of the palpation probe and the surface of the tissue.

5 9. The apparatus according to claim 1 including a second detector for measuring the color or temperature, or both, of the tissue.

10 10. The apparatus according to claim 1 wherein the controller produces a signal causing the actuator to move the palpation probe a distance, with a force, or for a time that is detected, or some combination thereof, against the surface of the tissue.

10 11. The apparatus according to claim 10 wherein the controller determines a characteristic value for the probed tissue from the detected distance, force, or time, or some combination thereof, traveled by the probe.

12. The apparatus according to claim 1 wherein the controller determines a characteristic value for the probed tissue from the detected distance traveled by the probe.

15 13. The apparatus according to claim 1 wherein the controller determines a characteristic value for the probed tissue from the detected distance traveled by the probe relative to a predetermined distance or time.

14. The apparatus according to claim 1 wherein the controller positions the palpation probe at a predetermined location against the tissue.

20 15. The apparatus according to claim 1 wherein the controller positions the longitudinal axis of the palpation probe substantially perpendicular to the surface of the tissue.

16. The apparatus according to claim 1 wherein the controller positions the palpation probe at a series of predetermined locations about the tissue.

17. The apparatus according to claim 16 wherein the series of predetermined locations encompasses the entire tissue area under investigation.

5 18. The apparatus according to claim 16 wherein the controller actuates the palpation probe at each location, and stores in a memory the location of the palpation probe, the detected distance, the velocity motion, or a characteristic value of the tissue, or some combination thereof.

10 19. The apparatus according to claim 18 wherein the controller creates a multi-dimensional model of the probed tissue using the characteristic value of the tissue.

20. The apparatus according to claim 18 wherein the controller determines a boundary using the characteristic value of the tissue.

21. The apparatus according to claim 1 including a tissue sampling device for obtaining a sample of the tissue.

15 22. The apparatus according to claim 21 wherein the sampling device is an invasive, or non-invasive device, or both.

23. The apparatus according to claim 21 wherein the sampling device is a needle, aspirator, coring device, ultrasound device, temperature sensing device, electromagnetic sensing device, or an impedance measurement device.

20 24. The apparatus according to claim 21 comprising an anesthetic delivery device to anesthetize an area proximate to the sampled tissue.

25. The apparatus according to claim 20 wherein the controller is in communication with the sampling device.

26. The apparatus according to claim 20 wherein the controller positions the sampling device at a preselected region of the tissue.

5 27. An apparatus for detecting differences in breast tissue, the apparatus comprising:

a palpation probe for palpating breast tissue;

a detector for detecting the distance traveled by or the velocity of motion of the palpation probe; and

10 a controller in communication with the palpation probe and the detector, the controller determining a breast tissue value for the probed breast tissue from the detected distance or velocity of motion.

28. The apparatus according to claim 27 wherein the palpation probe is operably connected with a solenoid.

15 29. The apparatus according to claim 27 wherein the controller positions the palpation probe at a predetermined location against the breast tissue .

30. The apparatus according to claim 27 wherein the controller applies a predetermined voltage to the solenoid to move the shaft a distance or speed determined by the resistance of the breast tissue .

20 31. The apparatus according to claim 27 wherein the detector includes an optical encoder or a magnetic encoder.

32. The apparatus according to claim 27 wherein the movement of the probe

is detected by an encoding device.

33. The apparatus according to claim 32 wherein the encoding device is an optical encoder or a magnetic encoder.

34. An apparatus for detecting differences in breast tissue, the apparatus comprising:

a detection device having a palpation probe for palpating breast tissue and a detector for detecting the distance traveled by and the velocity of motion of the palpation probe;

a location sensor for detecting the location of the breast tissue for producing an image map of the breast;

a controller in communication with the detection head and the location sensor, the controller positioning the palpation probe at a predetermined location along the breast tissue and directing the palpation probe against the breast tissue; and

a memory device for storing the distance traveled and velocity of motion of the probed breast tissue.

35. The apparatus of claim 34 wherein the location sensor includes an optical sensor.

36. The apparatus of claim 34 wherein the controller includes a microprocessor.

37. The apparatus of claim 34 wherein the location sensor is incorporated with the detection device.

38. The apparatus of claim 34 including a processor for determining a breast tissue value for the probed breast tissue from the detected distance and velocity of motion

of the palpation probe for producing a map of the breast tissue values.

39. The apparatus of claim 34 wherein the detection device includes a plurality of palpation probes.

40. An apparatus for detecting differences in breast tissue, the apparatus comprising a detection head having at least one palpation probe for palpating the breast tissue of a patient, and at least one detector for detecting the distance traveled by, or the velocity of motion of, or the time of motion of, said at least one palpation probe.

41. The apparatus of claim 40 including a location device having at least one sensor for determining the location of the breast tissue of the patient, the at least one sensor for mapping the surface of the breast tissue.

42. The apparatus of claim 41a including a controller in communication with the detection head and the location head for positioning the palpation probe at a predetermined location against the breast tissue and directing the palpation probe against the breast tissue.

43. The apparatus of claim 42 including a memory for storing the detected distance and velocity motion for the probed breast tissue.

44. The apparatus of claim 43 including a data processor for determining a breast tissue value for the probed breast tissue from the detected distance and velocity of motion of the palpation probe.

45. The apparatus of claim 44 including a breast tissue sampling device for sampling the breast tissue.

46. A method for detecting differences in breast tissue, the method comprising

the steps of:

palpating the breast tissue of a patient with a palpation probe;
detecting a distance traveled by, or a velocity of motion of, or a time in motion
of, the palpation probe; and
5 determining a breast tissue value for the probed breast tissue from the detected
distance traveled by, or the velocity of motion of, or the time in motion.

47. The method according to claim 46 wherein the palpation probe is moved
incrementally.

48. A method for detecting differences in breast tissue, the method comprising
10 the steps of:

- (a) positioning a palpation probe at a predetermined location against the breast
tissue of a patient;
- (b) actuating the palpation probe to move with a predetermined force against the
breast tissue;
- 15 (c) detecting the distance traveled by and the velocity of motion of the palpation
probe;
- (d) determining a characteristic value for the probed breast tissue from at least
one of the detected distance traveled, or the velocity of motion, or both;
and
- 20 (e) storing the palpation probe location, detected distance, velocity of motion, or
breast tissue value, or a combination thereof, in a memory.

49. The method of claim 48 which comprises repeating steps (c) through (e).

50. The method of claim 48 which comprises the step of positioning the
palpation probe at an alternate predetermined location against the breast tissue and
25 repeating steps of claim 48.

51. A method for mapping differences in breast tissue values, the method comprising the steps of:

- (a) positioning a palpation probe at a predetermined location against the breast tissue of a patient;
- 5 (b) orienting a longitudinal axis of the palpation probe at substantially normal incidence to the surface of the breast tissue;
- (c) actuating the palpation probe to move with a predetermined force against the breast tissue;
- 10 (d) detecting the distance traveled by and the velocity of motion of the palpation probe;
- (e) determining a breast tissue value for the probed breast tissue from at least one of the detected distance traveled or velocity of motion; and
- 15 (f) storing palpation probe location, detected distance, velocity of motion, and breast tissue value in a memory.

52. The method of claim 51 which comprises repeating steps (c) through (f).

53. The method of claim 51 which comprises the step of positioning the palpation probe at an alternate predetermined location against the breast tissue and repeating the steps of claim 51.

20 54. The method of claim 51 which comprises the step of identifying a region of breast tissue having a predetermined characteristic value.

55. The method of claim 54 which comprises the step of sampling the region of breast tissue with a sampling device.

25 56. An apparatus for detecting differences in body tissue, the apparatus comprising:

- at least one palpation probe for palpating body tissue;

at least one detector for detecting the distance traveled by, or the velocity of motion of the palpation probe; and
a controller in communication with the palpation probe and the at least one detector for measuring a characteristic value of the probed body tissue.

5 57. The apparatus of claim 56 wherein the controller determines whether the body tissue detected is skin, subcutaneous fatty tissue, benign tissue, or cancerous tissue, or a combination thereof.

 58. The apparatus of claim 56 wherein the body tissue detected is located on the face, abdomen, thigh, buttocks, or body.

10 59. The apparatus according to claim 56 wherein the palpation probe is operably connected to an electro-magnetic or a electro-mechanical actuator.

 60. The apparatus according to claim 56 wherein the detector is an optical encoder or a magnetic encoder.

15 61. The apparatus according to claim 56 including at least one sensor for mapping the surface of the body tissue.

 62. The apparatus according to claim 56 wherein the controller produces multi-dimensional mapping of the surface of the body tissue.

20 63. The apparatus according to claim 61 wherein the at least one sensor includes a camera, an autofocus system, a rangefinder, an acoustic sensor, or an optical sensor.

 64. The apparatus according to claim 61 wherein the at least one sensor determines the distance from the palpation probe to the body tissue.

65. The apparatus according to claim 61 wherein the at least one sensor determines the angle between the longitudinal axis of the palpation probe and surface of the probed body tissue.

5 66. The apparatus according to claim 56 including a second detector for measuring the color or the temperature of the probed body tissue.

67. The apparatus according to claim 56 wherein the controller delivers a signal to the actuator to move the palpation probe with a predetermined force against the body tissue.

10 68. The apparatus according to claim 56 wherein the controller determines a characteristic value for the probed body tissue from the detected distance relative to a predetermined distance.

69. The apparatus according to claim 56 wherein the controller positions the palpation probe at a predetermined location against the body tissue.

15 70. The apparatus according to claim 56 wherein the controller positions a longitudinal axis of the palpation probe substantially perpendicular to the surface of the body tissue.

71. The apparatus according to claim 56 wherein the controller positions the palpation probe at a series of predetermined locations across the body tissue.

20 72. The apparatus according to claim 71 wherein the series of predetermined locations encompasses the entire body area under investigation.

73. The apparatus according to claim 71 wherein the controller actuates the

palpation probe at each location and stores in a memory the location of the palpation probe, the detected distance, the velocity motion, or a characteristic value for the probed body tissue, or a combination thereof.

5 74. The apparatus according to claim 73 wherein the controller produces a multi-dimensional model of the characteristic values of the probed body tissue.

 75. The apparatus according to claim 73 wherein the controller determines a characteristic value for the probed body tissue.

10 76. The apparatus according to claim 56 including a body tissue sampling device for determining the cancerous state of the sampled body tissue.

 77. The apparatus according to claim 76 wherein the sampling device is an invasive device.

15 78. The apparatus according to claim 76 wherein the sampling device is a non-invasive device.

 79. The apparatus according to claim 76 wherein the sampling device is a biopsy device.

 80. The apparatus according to claim 79 wherein the biopsy device is an aspiration device.

20 81. The apparatus according to claim 79 wherein the biopsy device removes a tissue sample.

 82. The apparatus according to claim 81 wherein the biopsy device comprises a needle.

83. The apparatus according to claim 76 wherein the sampling device is an ultrasound device.

84. The apparatus according to claim 76 wherein the sampling device is a temperature measurement device.

5 85. The apparatus according to claim 76 wherein the sampling device is an electromagnetic sensing device.

86. The apparatus according to claim 85 wherein the sensing device comprises a sensor array.

10 87. The apparatus according to claim 86 wherein the sensor array measures low-level electric currents to produce an image of the electrical impedance within the body.

88. The apparatus according to claim 56 including an anesthetic delivery device to anesthetize an area proximate to the sampled body tissue.

15 89. The apparatus according to claim 56 wherein the controller is in communication with the sampling device.

90. The apparatus according to claim 56 wherein the controller determines the boundary of the detected characteristic values of body tissue.

20 91. The apparatus according to claim 73 wherein the controller determines whether the body tissue detected is skin, subcutaneous fatty tissue, benign tissue, or cancerous tissue, or a combination thereof.

92. The apparatus according to claim 56 including a liposuction device.

93. A method for mapping differences in characteristic values of body tissue, the method comprising the steps of:

- (a) positioning a palpation probe at a predetermined location against the body tissue of a patient;
- (b) actuating the palpation probe with an actuator to move with a predetermined force against the body tissue;
- (c) detecting the time traveled by, distance traveled by, or the velocity of motion of, the palpation probe;
- (d) determining a characteristic value of body tissue for the probed body tissue from at least one of the detected time traveled, distance traveled, or velocity of motion; and
- (e) storing palpation probe location, detected distance, velocity of motion, or the characteristic value of tissue, or any combination thereof, in a memory.

94. The method of claim 93 wherein the characteristic value of body tissue determined in step (d) corresponds to a predetermined characteristic value of tissue associated with a predetermined region of the body.

95. The method of claim 94 wherein the predetermined characteristic value of tissue corresponds to skin, subcutaneous fatty tissue, benign tissue, or cancerous tissue.

96. The method of claim 94 wherein the predetermined region of the body corresponds to the face, abdomen, thigh, or buttocks.

97. The method of claim 93 which comprises the step of removing tissue having a predetermined characteristic value.

98. The method of claim 97 wherein the tissue removed has a predetermined characteristic value corresponding to skin, subcutaneous fatty tissue, benign tissue, or cancerous tissue.

99. The method of claim 97 wherein the tissue is removed by means of a laser,
5 mechanical, chemical, or cryogenic device.

100. A method for mapping differences in characteristic values of body tissue, the method comprising the steps of:

- (a) positioning a palpation probe at a predetermined location against the body tissue of a patient;
- (b) actuating the palpation probe with an actuator to move with a predetermined force against the body tissue; and
- (c) detecting the time traveled by, distance traveled by, or the velocity of motion of, the palpation probe.

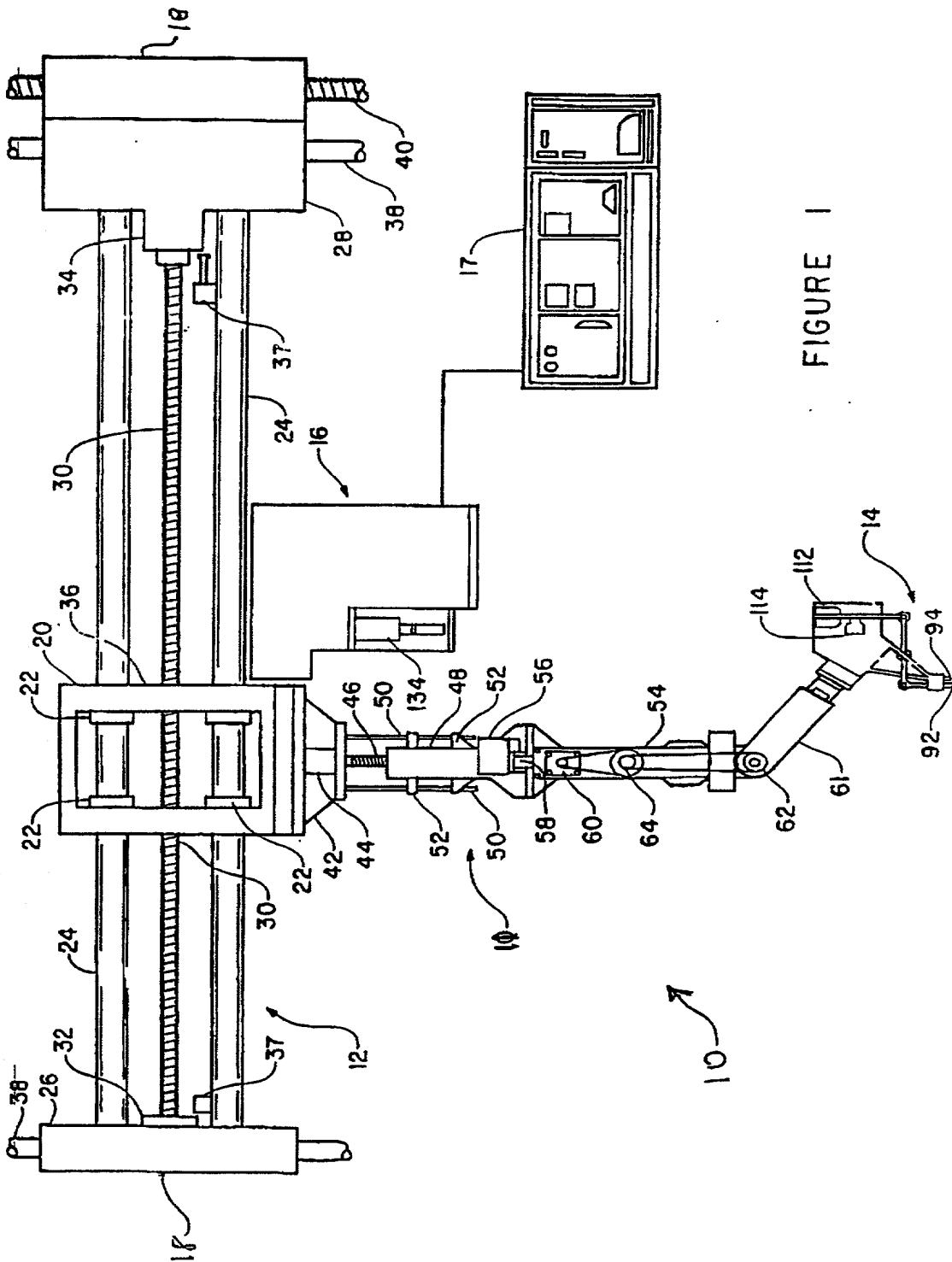
101. The method of claim 100 including the step of determining a characteristic value of body tissue for the probed body tissue from at least one of the detected time traveled, distance traveled, or velocity of motion.

102. The method of claim 101 including the step of storing palpation probe location, detected distance, velocity of motion, or the characteristic value of tissue, or any combination thereof, in a memory.

103. The apparatus according to claim 4 wherein one sensor includes a digital camera and grid to establish investigation coordinates for use in comparing measurements made at some other time.

104. The apparatus according to claim 34 wherein the sensor includes a digital camera and grid to establish investigation coordinates for use in comparing

105. The apparatus according to claim 2 wherein the palpation probe includes an end isolator composed of an electrically insulating material.



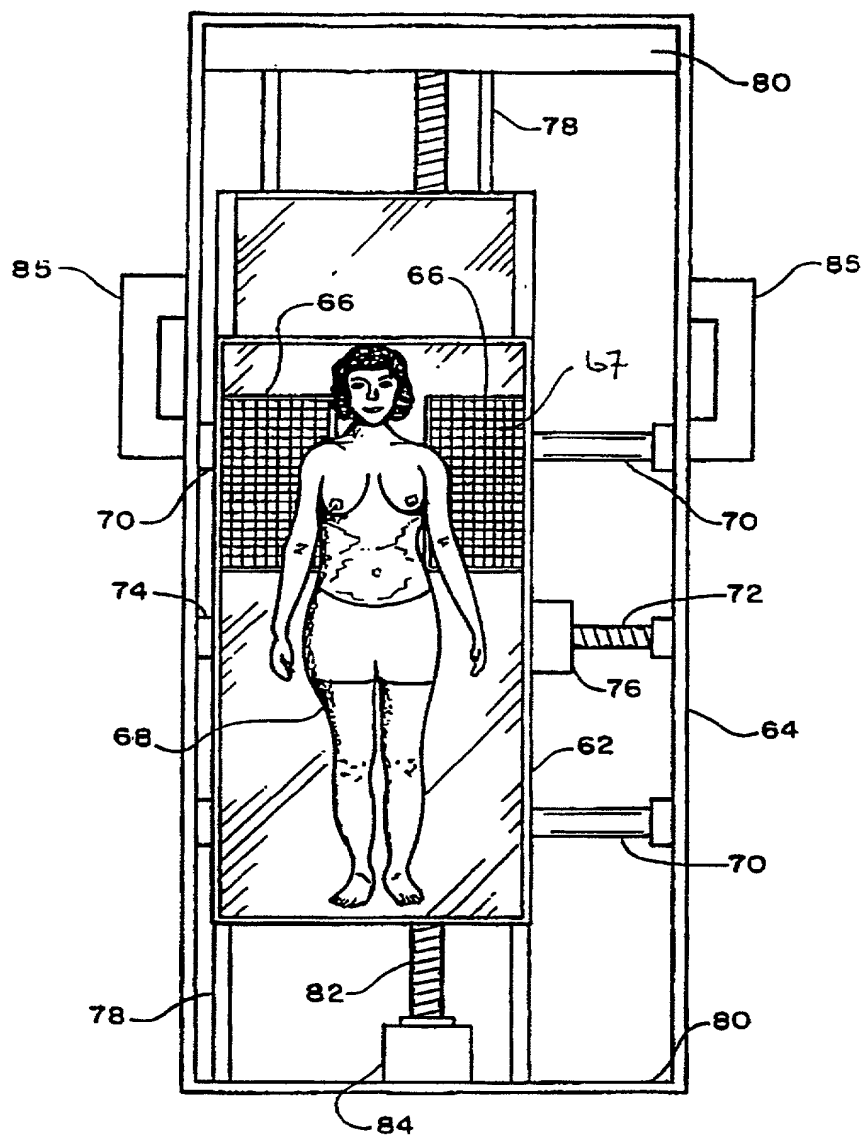


FIGURE 2

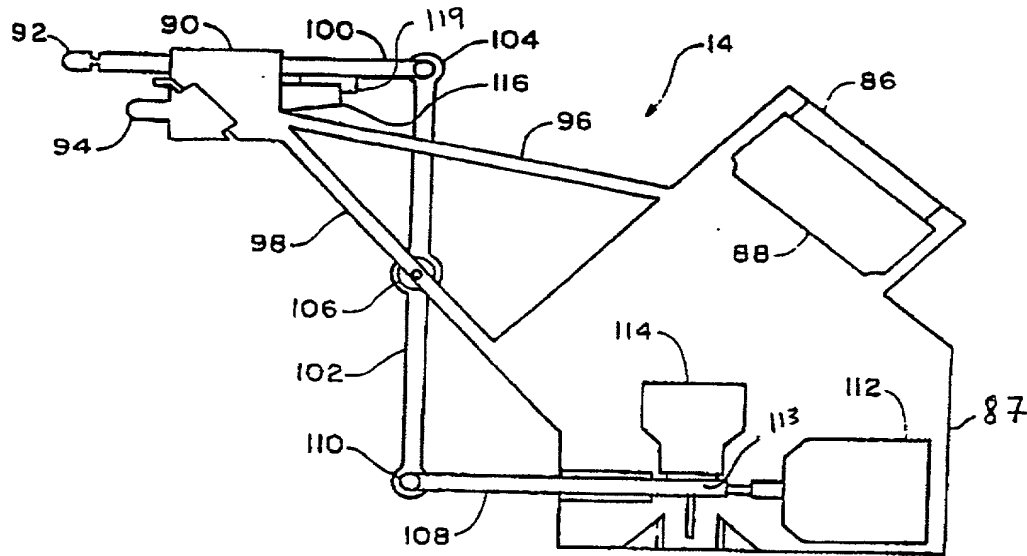


FIGURE 3

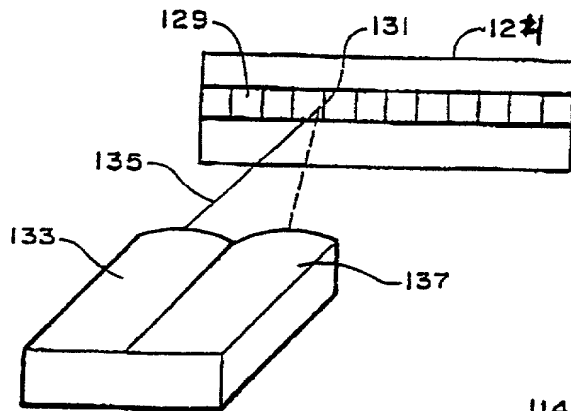


FIGURE 4A

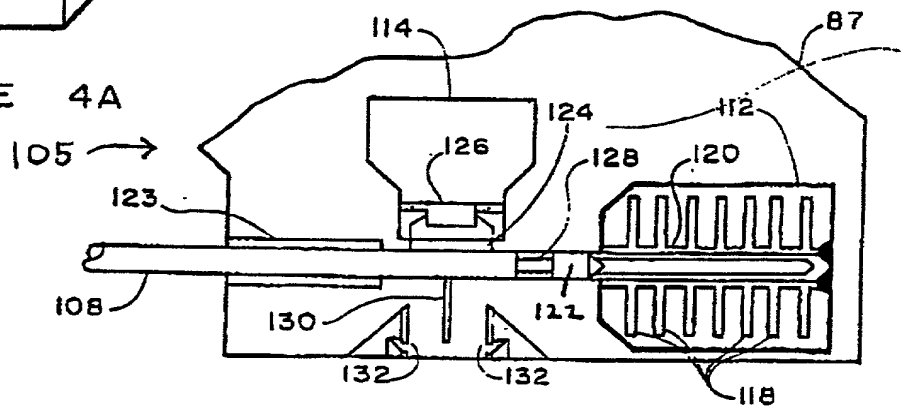


FIGURE 4

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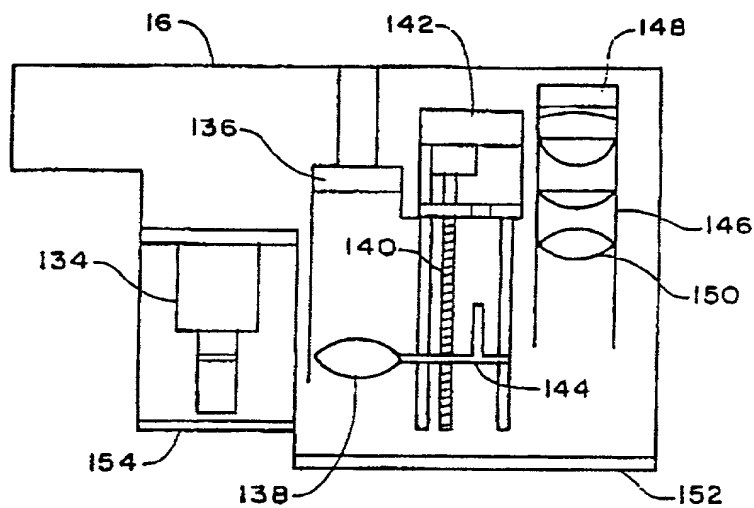


FIGURE 5

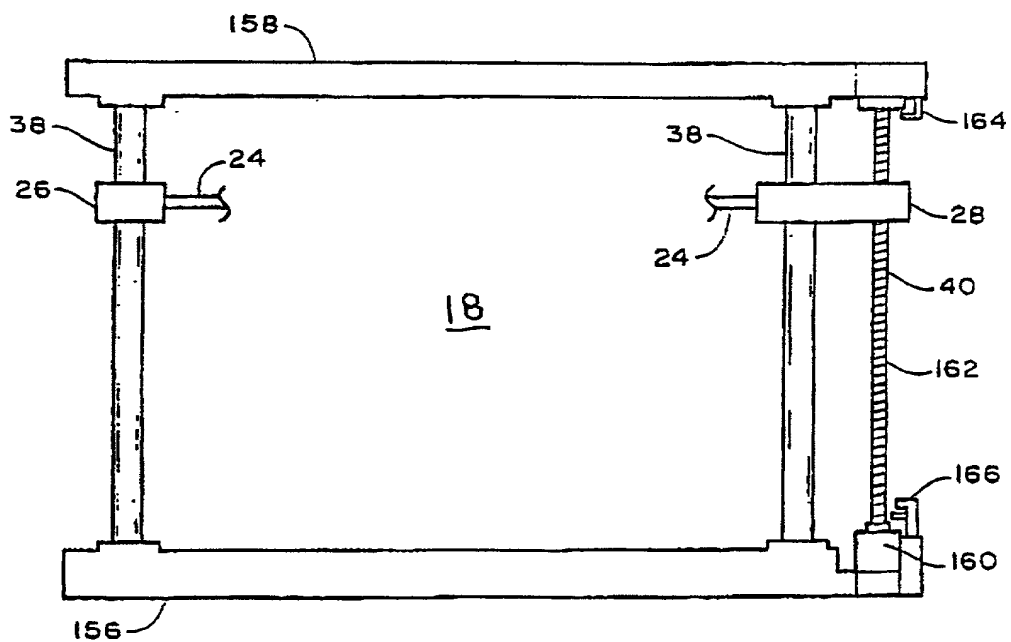
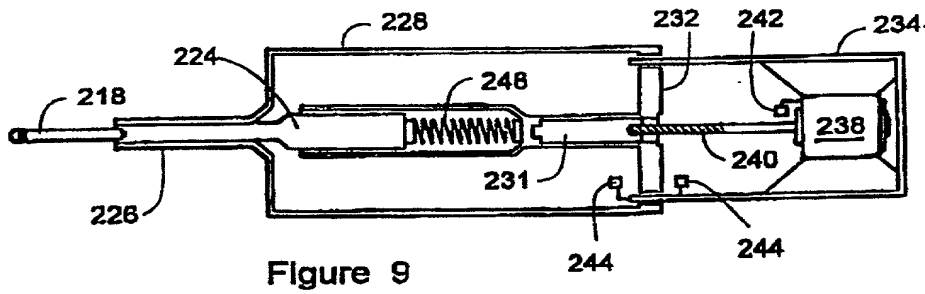
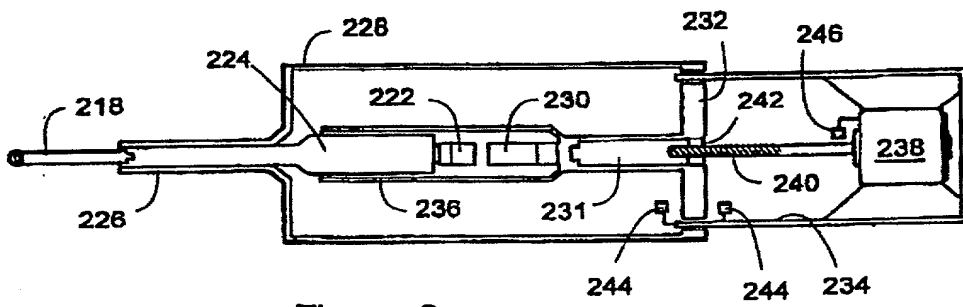
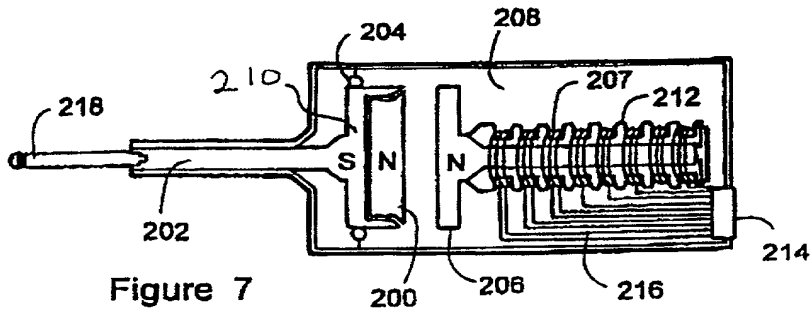


FIGURE 6



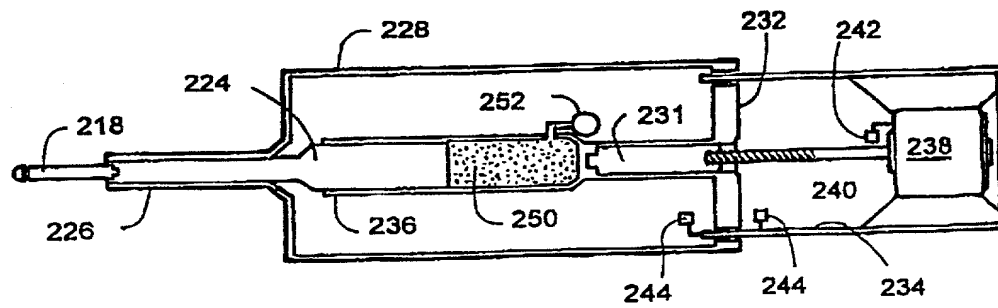


Figure 10

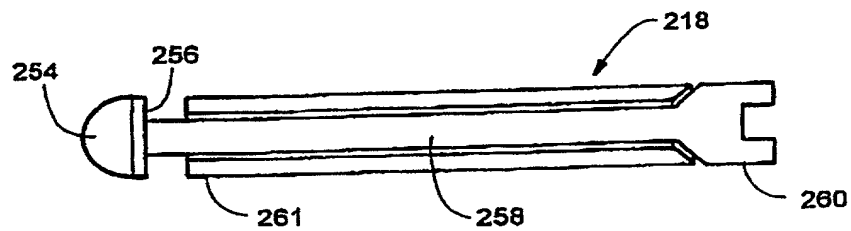


Figure 11

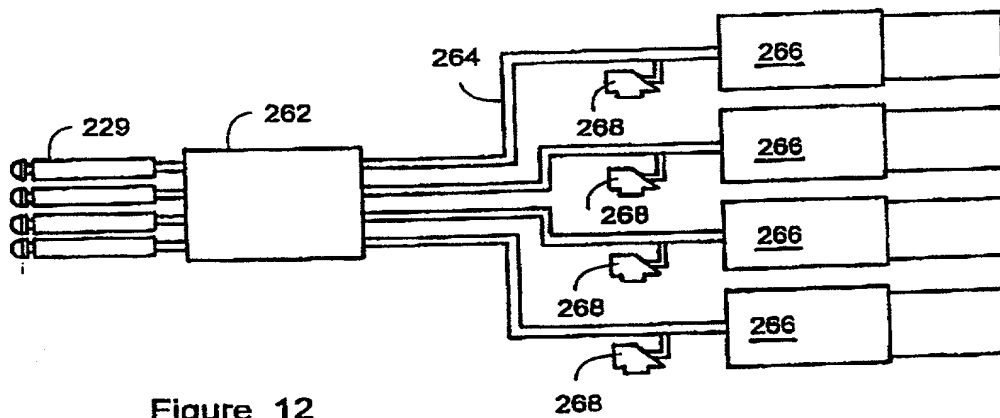
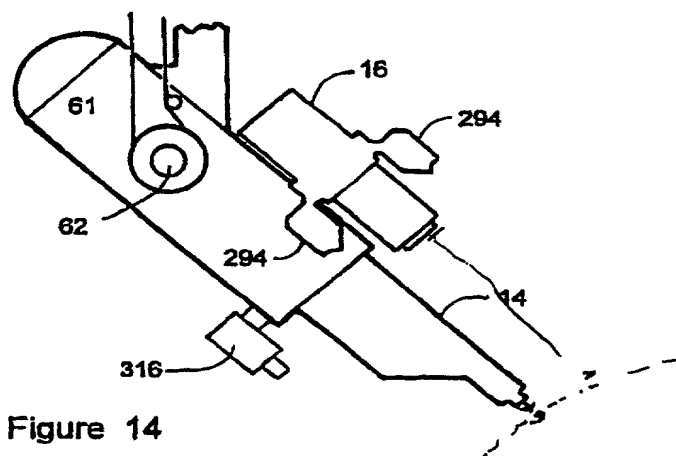
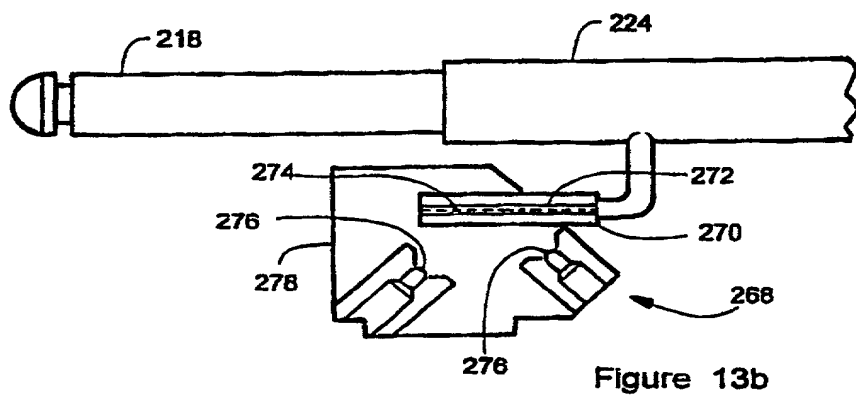
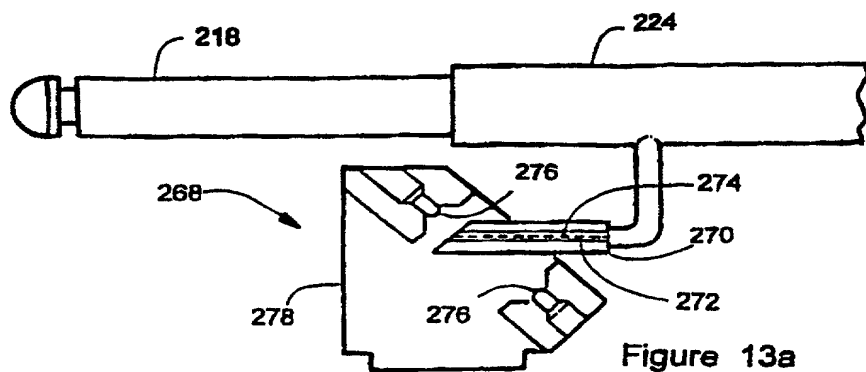
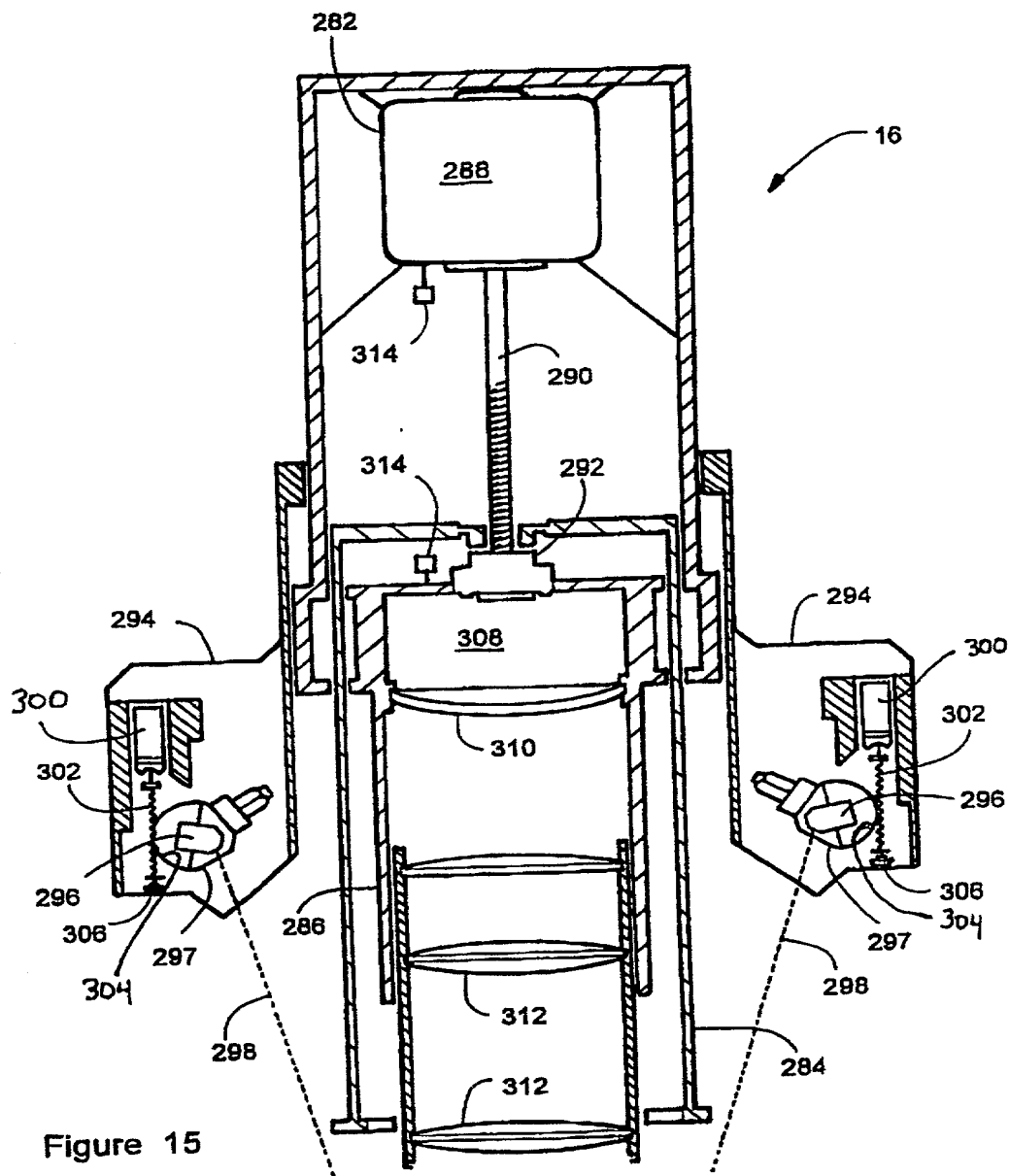


Figure 12

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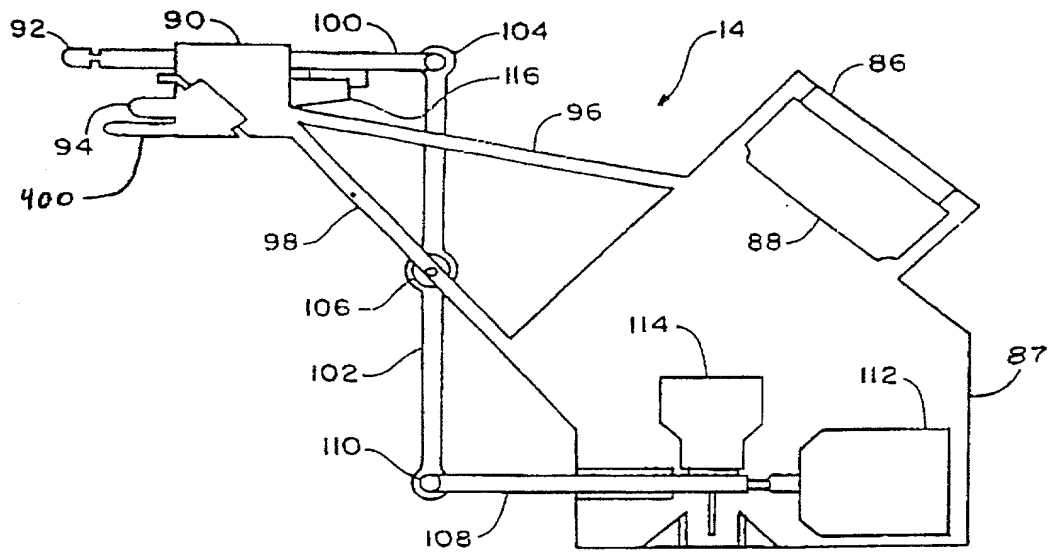


FIGURE 16

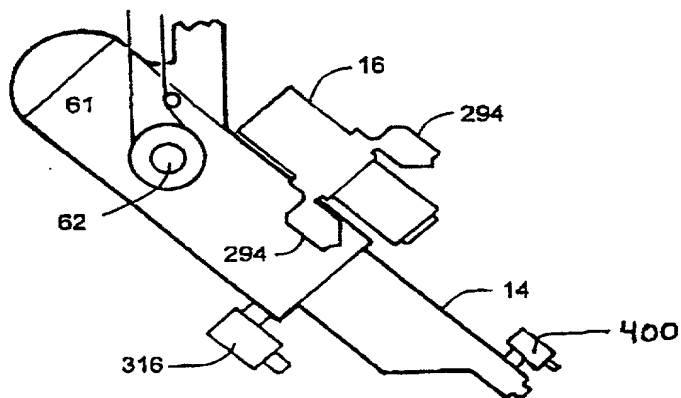


Figure 17

FIG 18 A

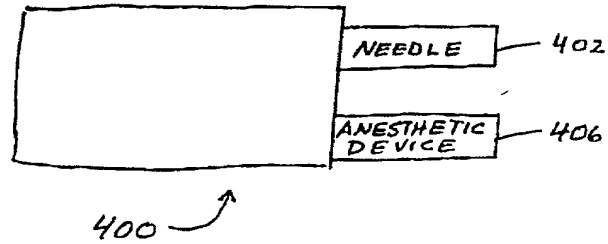


FIG 18 B

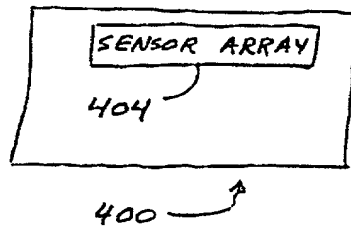
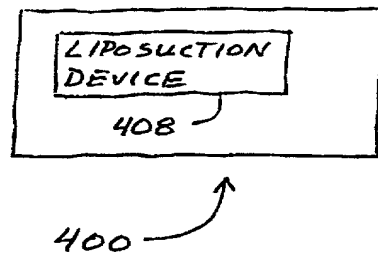


FIG 18 C



DECLARATION AND POWER OF ATTORNEY

As a below named inventor, I hereby declare that:

This declaration is for a national stage of PCT application.

My residence, post office address and citizenship are stated below next to my name.

I believe I am an original inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled:

Apparatus and Method for Detecting Anomalies in Human Tissues

the specification of which (check one)

The specification was described and claimed in PCT International Application PCT/US00/2341 filed January 29, 2000.

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56(a).

PRIORITY CLAIM UNDER 35 USC § 119

PRIORITY FOREIGN APPLICATION(S) UNDER 35 USC § 119 (a)-(d)

I hereby claim foreign priority benefits under Title 35, United States Code §119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

DETAILS OF FOREIGN APPLICATION FROM WHICH PRIORITY IS CLAIMED UNDER 35 USC 119 (a)-(d)			
Country	Application No.	Date of Filing (day, month, year)	Date of Issue (day, month, year)

**PRIORITY U.S. PROVISIONAL APPLICATIONS(S)
UNDER 35 USC ' 119 (e)**

I hereby claim the benefit under Title 35, United States Code, ' 119(e) of any United States provisional application(s) listed below:

U.S. PROVISIONAL APPLICATION NO.	FILING DATE

**PRIORITY U.S./PCT APPLICATIONS
UNDER 35 USC ' 120**

I hereby claim the benefit under Title 35, United States Code, ' 120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, ' 112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, ' 1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

PRIOR U.S. APPLICATIONS OR PCT INTERNATIONAL APPLICATIONS DESIGNATING THE U.S. FOR BENEFIT UNDER 35 USC ' 120				
U.S. Application No.	U.S. Filing Date	Patented	Pending	Abandoned
09/241,193	February 1, 1999		X	
08/957,648	October 24, 1997	X		
PCT APPLICATIONS DESIGNATING THE U.S.				
PCT Application No.	PCT FILING DATE	U.S. Application Nos. Assigned (if any)		
PCT/US00/02341	January 29, 2000			
SEE 35 USC ' 119 PRIORITY CLAIM, IF ANY, FOR ABOVE LISTED U.S./PCT APPLICATIONS				

2 And I hereby appoint Alfred W. Zaher, Registration No. 42,248 and Bruce D. George, Registration No. 43,631 as my attorneys or agents with full power of substitution and revocation, to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith.

Address all correspondence to Saul, Ewing LLP, Centre Square West, 1500 Market Street, 38th Floor, Philadelphia, Pennsylvania 19102-2186. Address all telephone calls to Alfred W. Zaher at (215) 972-8385 (Fax: 215-972-2291).

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

1-0
Full name of first inventor, Farid Souluer
Inventor's signature [Signature]
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